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(54) **Title:** DEVICES, SYSTEMS, AND METHODS FOR PROSTHESIS DELIVERY AND IMPLANTATION

(57) **Abstract:** Devices, systems, and methods use a catheter device sized and configured for introduction to a targeted site in a hollow body organ or blood vessel. The catheter device includes a first release mechanisms coupled to the prosthesis to secure at least one region of the prosthesis to the catheter shaft, and a second release mechanism coupled to the prosthesis in cooperation with the first release mechanism to prevent full release of the at least one region of the at least one region of the prosthesis from the catheter shaft after actuation of the first release mechanism. A fastening device sized and configured- for introduction to the targeted site in the hollow body organ or blood vessel occupied by the catheter device, includes an actuator to deploy a fastener in the at least one region of the prosthesis after actuation of the first release mechanism and before actuation of the second release mechanism.

DEVICES, SYSTEMS, AND METHODS FOR PROSTHESIS DELIVERY AND IMPLANTATION

Related Applications

This application is a continuation-in-part of co-pending United Stated Patent Application Serial No. 11/254,619, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Guiding an Operative Tool Into an Interior Body Region," which is incorporated herein by reference. This application also is a continuation-in-part of co-pending United Stated Patent Application Serial No. 10/692,283, filed October 23, 2003, and entitled "Prosthesis Delivery Systems and Methods," which claims the benefit of United States Provisional Patent Application Serial No. 60/488,753, filed July 21, 2003, and entitled "Endoprosthesis Delivery Systems and Methods." This application also is a continuation-in-part of co-pending United Stated Patent Application Serial No. 10/786,465, filed February 25 2004, and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ." This application is also a continuation-in-part of co-pending United States Patent Application 11/693,255, filed June 24, 2005, entitled "Multi-Lumen Prosthesis Systems and Methods," which is a division of United States Patent Application Serial No. 10/693,255, filed 24 October 2003

(now United States Patent 6,929,661), which claims the benefit of United States Provisional Patent Application Serial No. 60/489,011, filed July 21, 2003, and entitled "Bifurcated Prosthesis Systems and Methods." This application also is a continuation-in-part of co-pending United Stated Patent Application Serial No. 10/307,226, filed 29 November 2002, and entitled "Intraluminal Prosthesis Attachment Systems and Methods." This application is also a continuation-in-part of copending United States Patent Application Serial Number 10/669,881, entitled "Catheter-Based Fastener Implantation Apparatus and Methods with Implantation Force Resolution." This application is also a continuation-in-part of copending United States Patent Application Serial No. 11/166,411, filed June 24, 2005, entitled "Endovascular Aneurysm Repair System," which is a division of United Stated Patent Application Serial No. 10/271,334, filed 15 October 2002 (now United States Patent No. 6,960,217), which claims the benefit of United States Provisional Patent Application Serial No. 60/333,937, filed 28 November 2001, and entitled "Endovascular Aneurysm Repair System." Each of the preceding applications is incorporated herein by reference.

Field of the Invention

The invention relates generally to devices, systems, and methods for the delivery and implantation of a prosthesis to a targeted site within the body, e.g., for the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel.

Background of the Invention

The weakening of a vessel wall from damage or disease can lead to vessel dilatation and the formation of an aneurysm. Left untreated, an aneurysm can grow in size and may eventually rupture.

For example, aneurysms of the aorta primarily occur in the abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation. Aneurysms can also occur in the thoracic region between the aortic arch and renal arteries. The rupture of an aortic aneurysm results in massive hemorrhaging and has a high rate of mortality.

Open surgical replacement of a diseased or damaged section of vessel can eliminate the risk of vessel rupture. In this procedure, the diseased or damaged section of vessel is removed and a prosthetic prosthesis, made either in a straight or bifurcated configuration, is installed and then permanently attached and sealed to the ends of the native vessel by suture. The prosthetic prosthesis for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The prosthesis are longitudinally unsupported so they can accommodate changes in the morphology of the aneurysm and native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co-morbidities.

Endovascular aneurysm repair has been introduced to overcome the problems associated with open surgical repair. The aneurysm is bridged with a vascular prosthesis, which is placed intraluminally. Typically these prosthetic prostheses for aortic aneurysms are delivered collapsed on a catheter through the femoral artery. These prostheses are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel. Unlike open surgical aneurysm repair, intraluminally deployed prostheses are not sutured to the native vessel, but rely

on either barbs extending from the stent, which penetrate into the native vessel during deployment, or the radial expansion force of the stent itself is utilized to hold the prosthesis in position. These prosthesis attachment means do not provide the same level of attachment when compared to suture and can damage the native vessel upon deployment.

Accordingly, there is a need for improved prosthesis delivery devices, systems, and methods that deliver a prosthetic graft to a body lumen, the prosthesis being able to adapt to changes in aneurysm morphology and able to be deployed safely and without damage to the native vessel.

Summary of the Invention

The devices, systems, and methods for delivering and implanting radially expandable prostheses in the body lumens and hollow body organ are described. In particular, the present invention provides improved devices, systems, and methods for implanting vascular prostheses into blood vessels, including both arterial and venous systems. In the exemplary embodiments, prostheses are placed in vasculature to reinforce aneurysms, particularly abdominal aortic aneurysms.

According to one aspect of the invention, devices, systems and methods position a deployment catheter at a targeted site in a hollow body organ or blood vessel. The deployment catheter carries an expandable endovascular prosthesis. The devices, systems and methods actuate a first release mechanism on the deployment catheter to allow at least some expansion of at least one region of the prosthesis at the targeted site without fully releasing the one region of the prosthesis from the deployment catheter. After actuating the first release mechanism, the devices, systems and methods apply a fastener to fasten the at least one region of the

prosthesis to the targeted site. After applying the fastener, the devices, systems and methods actuate a second release mechanism on the deployment catheter to fully release the at least one region of the prosthesis from the deployment catheter.

According to another aspect of the invention, devices, systems and methods position a deployment catheter at a targeted site in a hollow body organ or blood vessel. The deployment catheter carries an expandable endovascular prosthesis. The devices, systems and methods actuate a first release mechanism on the deployment catheter to allow at least some expansion of the proximal region of the prosthesis at the targeted site without fully releasing the proximal end of the prosthesis from the deployment catheter. After actuating the first release mechanism, the devices, systems and methods apply a fastener to fasten the proximal end the prosthesis to the targeted site. After applying the fastener, the devices, systems and methods actuate a second release mechanism on the deployment catheter to fully release the proximal end of the prosthesis from the deployment catheter. After applying the fastener, the devices, systems and methods actuate a third release mechanism on the deployment catheter to fully release the distal end of the prosthesis from the deployment catheter.

The devices, systems, and methods make possible longitudinal and/or rotational adjustment of the position and orientation of the prosthesis before prior to applying a fastener. The devices, systems, and methods also make possible retaining control of the prosthesis, both proximally and distally, while a fastener is applied.

Other features and advantages of the invention shall be apparent based upon the accompanying description,

drawings, and claims.

Brief Description of the Drawings

Fig. 1 is a perspective view of one embodiment of a prosthesis deployment catheter shown positioned within an abdominal aortic aneurysm.

Fig. 2 is a perspective view of one embodiment of the deployment of a prosthesis within the aneurysm of Fig. 1, with the jacket partially retracted.

Fig. 3 is a perspective view of one embodiment of the deployment of a prosthesis within the aneurysm of Fig. 1, with the jacket fully retracted and showing radial expansion of the proximal end.

Fig. 4 is a perspective view of one embodiment of the completed deployment of a multi-lumen prosthesis within the aneurysm of Fig. 1.

Fig. 5 is a perspective view of an alternative embodiment of the completed deployment of a single lumen prosthesis within the aneurysm of Fig. 1.

Fig. 6 is a side view of the multi-lumen prosthesis assembly that embodies features of the invention, the multi-lumen prosthesis assembly shown with lumen extensions.

Fig. 7A is a side view of the main body component of the multi-lumen prosthesis assembly.

Fig. 7B is an enlarged view showing detail of the distal stent curved apices of the multi-lumen prosthesis shown in Fig. 7A.

Fig. 7C is a side view of one embodiment of the prosthesis septum, showing stitches and weaving to form the septum.

Fig. 7D is a side view of an alternative embodiment of the main body component of the multi-lumen prosthesis assembly of Fig. 7A, showing the main body prosthesis having a second lumen extending beyond the first lumen.

Fig. 8A is a section view of the distal end of the

main body component of the multi-lumen prosthesis taken generally along line 8A-8A of Fig. 6.

Fig. 8B is a section view of the proximal end of the main body component of the multi-lumen prosthesis taken generally along line 8B-8B of Fig. 6.

Fig. 9A is a side view of a prosthesis lumen extension.

Fig. 9B is an enlarged view showing detail of the securing stent curved apices of the lumen extension shown in Fig. 9A.

Fig. 9C is a side view of one extension lumen coupled to the main body component of the multi-lumen prosthesis.

Fig. 9D is an enlarged view showing detail of the curved apices of both the securing stent of the lumen extension coupled to the distal stent of the main body prosthesis, as shown in Fig. 9C.

Fig. 10A is a side view of an alternative embodiment of the prosthesis lumen extension of Fig. 9A, and shows securing stents without deflected apices.

Fig. 10B is an enlarged view showing detail of the securing stents of the lumen extension shown in Fig. 10A.

Fig. 10C is a side view showing the alternative embodiment of the prosthesis lumen extension of Fig. 10A coupled to the main body component of the multi-lumen prosthesis.

Fig. 10D is an enlarged view showing detail of the securing stents of the alternative embodiment of the lumen extension coupled to the distal stent of the main body prosthesis, as shown in Fig. 10C.

Fig. 11 is a perspective view of a prosthesis deployment catheter that embodies features of the invention.

Fig. 12 is a side view of one embodiment of the proximal end of the deployment catheter of Fig. 11.

Fig. 13 is a side view of the proximal end of the deployment catheter of Fig. 11, and showing a jacket covering components of the deployment catheter.

Fig. 14A is a side view of the proximal end of the deployment catheter of Fig. 11, and showing the jacket covering the main body component of the multi-lumen prosthesis prior to deployment.

Fig. 14B is a perspective view of an alternative embodiment of the deployment catheter jacket of Fig. 11 showing structural reinforcement.

Fig. 15 is a section view of the lumens in the central shaft deployment catheter taken generally along line 15-15 of Fig. 12.

Fig. 16 is a side view of the catheter tip and central shaft of the deployment catheter showing the catheter tip lumen and central shaft lumen.

Fig. 17 is a perspective view of the main body component of the multi-lumen prosthesis positioned on the proximal end of the deployment catheter prior to deployment, and showing the first proximal retaining means in a compressed condition.

Fig. 18A is a side view of one embodiment of a suture loop path around the main body component of the multi-lumen prosthesis.

Fig. 18B is a side view of an alternative embodiment of a suture loop path around the multi-lumen prosthesis of Fig. 18A, showing multiple suture loops.

Fig. 19 is a perspective view of the main body component of the multi-lumen prosthesis positioned on the proximal end of the deployment catheter showing the first proximal retaining means released and the proximal end of the main body component expanded.

Fig. 20 is a side view of a portion of the distal end of the deployment catheter showing one embodiment of a first proximal releasing means and a first proximal

release wire.

Fig. 21 is a side view of a portion of the proximal end of the deployment catheter showing detail of the first proximal release hub and central shaft lumens.

Fig. 22 is a side view of a portion of the distal end of the deployment catheter showing detail of one embodiment of the second proximal releasing means.

Fig. 23 is a side view showing detail of the stabilizing arms in a pre-deployment configuration, the proximal ends of the stabilizing arms being arched back generally toward a first proximal release hub.

Fig. 24 is a side view of the stabilizing arms of Fig. 23 in a pre-deployment configuration with the deployment catheter and multi-lumen prosthesis positioned within the descending aorta, and showing the proximal ends of the stabilizing arms coupled to the proximal end of the main body prosthesis.

Fig. 25 is a side view showing detail of stabilizing arms coupled to the proximal end of the main body prosthesis, showing the second proximal release wire stitched or otherwise extended through a stabilizing arm aperture and through the prosthesis material, releasably securing the stabilizing arms to the main body prosthesis.

Fig. 26 is a side view of the stabilizing arms of Fig. 23 in a post-deployment configuration with the deployment catheter and multi-lumen prosthesis positioned within the descending aorta, and showing the proximal ends of the stabilizing arms released from the proximal end of the main body prosthesis.

Fig. 27 is a section view of the proximal end of the deployment catheter shaft taken generally along line 27-27 of Fig. 23.

Fig. 28 is a side view of the distal end of the main body prosthesis positioned on the deployment catheter

central shaft prior to deployment of the distal retaining means.

Fig. 29A is a side view of one embodiment of a suture loop path around the distal end of the multi-lumen prosthesis.

Fig. 29B is a side view of an alternative embodiment of a suture loop path around the distal end of the multi-lumen prosthesis of Fig. 29A, showing multiple suture loops.

Fig. 30 is a side view of the distal end of the main body component of the multi-lumen prosthesis positioned on the deployment catheter shaft of Fig. 28, showing the distal retaining means released and the distal end of the main body component expanded.

Fig. 31 is a side view of a portion of the proximal end of the deployment catheter showing detail of the distal releasing means and central shaft lumens.

Fig. 32 is a side view of an alternative embodiment of the distal end of the main body prosthesis positioned on the deployment catheter central shaft prior to deployment of the distal retaining means.

Fig. 33 is a side view of the distal end of the main body component of the multi-lumen prosthesis positioned on the deployment catheter shaft of Fig. 32, showing the alternative distal retaining means released and the distal end of the main body component expanded.

Fig. 34 is a perspective view of a first side of the deployment catheter handle assembly that embodies features of the invention.

Fig. 35 is a perspective view of a second side of the deployment catheter handle assembly that embodies features of the invention.

Fig. 36 is a top view of the deployment catheter handle assembly of Fig. 34.

Fig. 37 is a section view of the deployment catheter

handle assembly of Fig. 34 taken generally along line 37-37 of Fig. 36.

Fig. 38 is a section view of the deployment catheter handle assembly of Fig. 34 taken generally along line 38-38 of Fig. 36.

Fig. 39 is a top view of a portion of the deployment catheter handle assembly of Fig. 34 showing the jacket retraction means prior to jacket retraction.

Fig. 40 is a top view of a portion of the deployment catheter handle assembly of Fig. 39 showing the jacket retraction means after the jacket has been retracted.

Fig. 41 is a perspective view of a second side of one embodiment of a rack and pinion mechanism and a release system positioned within the deployment catheter handle assembly.

Fig. 42 is a perspective view of a second side of one embodiment of a rack and pinion mechanism and a release system positioned within the deployment catheter handle assembly.

Fig. 43 is a perspective view showing detail of the release system positioned within the deployment catheter handle assembly.

Fig. 44A is a perspective view of a lumen extension deployment catheter that embodies features of the invention.

Fig. 44B is a perspective view of the lumen extension deployment catheter shown in Fig. 44A, and showing a stationary outer jacket and a hemostatic valve.

Fig. 45A is a side view of one embodiment of the proximal end of the lumen extension deployment catheter of Fig. 44.

Fig. 45B is a side view of an alternative embodiment of the proximal end of the lumen extension deployment catheter of Fig. 45A, and shows an optional distal retaining and releasing means.

Fig. 46A is a side view of a proximal section of the lumen extension deployment catheter of Fig. 45A, and showing a jacket covering the lumen extension positioned on the catheter shaft prior to deployment.

Fig. 46B is a side view of an alternative embodiment of a proximal section of the lumen extension deployment catheter of Fig. 45B, and showing a jacket covering the lumen extension positioned on the catheter shaft prior to deployment and including a distal retaining means.

Fig. 46C is a perspective view of an alternative embodiment of the lumen extension deployment catheter jacket of Fig. 44 showing structural reinforcement.

Fig. 47A is a section view of the lumen extension deployment catheter shaft of Fig. 45A taken generally along line 47A-47A of Fig. 45A.

Fig. 47B is a section view of an alternative embodiment of the lumen extension deployment catheter shaft of Fig. 45B taken generally along line 47B-47B of Fig. 45B.

Fig. 48A is a side view of one embodiment of a suture loop path around the proximal end of the lumen extension.

Fig. 48B is a side view of one embodiment of a suture loop path around the distal end of the lumen extension.

Fig. 48C is a side view of an alternative embodiment of a suture loop path around the proximal or distal end of the lumen extension shown in Figs. 48A and 48B, and shows multiple suture loops.

Fig. 49A is side view of the lumen extension deployment catheter handle assembly of Fig. 44.

Fig. 49B is a side view of an alternative embodiment of the lumen extension deployment catheter handle assembly of Fig. 44, and showing and additional slide knob for an optional distal releasing means.

Fig. 50 is top view of the lumen extension deployment catheter handle assembly of Fig. 44.

Fig. 51 is a perspective view of one embodiment of the release system positioned within the handle assembly of the lumen extension deployment catheter.

Fig. 52 is an enlarged perspective view of one embodiment of a helical fastener that can be used in association with a fastener tool or device shown in Fig. 53.

Fig. 53 is a perspective view of a fastener tool that embodies features of the invention.

Fig. 54 is a perspective view of the handle assembly of the fastener tool of Fig. 53.

Fig. 55 is a perspective view of a steerable guide device that embodies features of the invention.

Fig. 56 is a perspective view of the handle assembly of the steerable guide device of Fig. 55.

Fig. 57 is a perspective view of an obturator or dilator that may be used in conjunction with the steerable guide device of Fig. 55.

Fig. 58 is a perspective view of one embodiment of a prosthesis deployment catheter shown positioned within an abdominal aortic aneurysm.

Fig. 59 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, with the jacket partially retracted.

Fig. 60 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, with the jacket fully retracted but prior to the release of the proximal or distal retaining means.

Fig. 61 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, with the jacket fully

retracted but prior to the release of the proximal or distal retaining means and showing an alternative embodiment of the distal retaining means.

Fig. 62 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the first proximal retaining means released and the proximal end of the main body component expanded.

Fig. 63 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing a second guide wire positioned through the main body prosthesis lumen.

Fig. 64 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the steerable guide and obturator positioned on the second guide wire and through the main body prosthesis lumen.

Fig. 65 is an enlarged perspective view of the deployment of the main body component of the multi-lumen prosthesis within the descending aorta, and showing the steerable guide device and the fastener tool just prior to fastening a helical fastener through the prosthesis material and into tissue.

Fig. 66 is an enlarged perspective view of the deployment of the main body component of the multi-lumen prosthesis within the descending aorta, and showing the steerable guide device and the fastener tool just after fastening a helical fastener through the prosthesis material and into tissue.

Fig. 67 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the deflected end of the steerable guide device and the fastener tool after being repositioned for deployment of an additional

helical fastener.

Fig. 68 is an enlarged perspective view of the deployment of the main body component of the multi-lumen prosthesis within the descending aorta, and showing one embodiment of a fastener deployment pattern.

Fig. 69 is a perspective view of the deployment of a lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the lumen extension catheter being positioned partially within a prosthesis lumen.

Fig. 70 is a perspective view of the deployment of the lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the jacket retracted from the lumen extension deployment catheter and prior to the release of a proximal retaining means.

Fig. 71 is a perspective view of the deployment of the lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the lumen extension coupled to and fully expanded within a lumen of the main body component after the release of the proximal retaining means.

Fig. 72 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the lumen extension deployment catheter removed and the stabilizing arms of the main body deployment catheter released.

Fig. 73 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the distal retaining means released and the distal end of the main body prosthesis expanded.

Fig. 74 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the

withdrawal of the rejacketed main body deployment catheter over the fist guide wire.

Fig. 75 is a perspective view of the deployment of a second lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the lumen extension catheter being positioned partially within a prosthesis lumen.

Fig. 76 is a perspective view of the deployment of the second lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the jacket retracted from the lumen extension deployment catheter and prior to the release of a proximal retaining means.

Fig. 77 is a perspective view of the deployment of the second lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the second lumen extension coupled to and fully expanded within a lumen of the main body component after the release of the proximal retaining means.

Fig. 78 is a perspective view of one embodiment of the completed deployment of the multi-lumen prosthesis within the aneurysm of Fig. 58.

Fig. 79A is an enlarged perspective view of an alternative embodiment of a helical fastener that can be used in association with a fastener tool or device shown in Fig. 53.

Fig. 79B is an enlarged top view of the alternative fastener of Fig. 79A showing a "D" shape.

Fig. 80 is an enlarged perspective view of the deployment of the main body component of the multi-lumen prosthesis within the descending aorta, and showing the steerable guide device and the fastener tool having an alternative fastener driver just prior to fastening the helical fastener of Fig. 79A through the prosthesis material and into tissue.

Fig. 81 is an enlarged perspective view of the fastener driver and fastener of Fig. 80, and showing the fastener rotating off of the fastener carrier.

Fig. 82A is an enlarged side view of the fastener driver of Fig. 80, and showing a fastener positioned on the fastener carrier and within a threaded fastener housing, and also showing the fastener latch feature.

Fig. 82B is an enlarged side view of the fastener driver of Fig. 80, and showing a fastener on the carrier and rotating off the carrier and showing the pivoting of the fastener latch.

Fig. 82C is an enlarged side view of the fastener driver of Fig. 80, and showing a fastener positioned on the fastener carrier and within a threaded fastener housing, and also showing an alternative fastener latch feature.

Fig. 83 is a perspective view of one embodiment of a fastener cassette with fasteners releasably positioned with a fastener receptacle.

Fig. 84 is a perspective view of an alternative embodiment of a fastener cassette of Fig. 82.

Fig. 85 is a perspective view showing the fastener tool positioned on a fastener cassette for removal of a fastener from the cassette and positioning the fastener within the fastener driver.

Fig. 86 is a perspective view showing the fastener tool with a fastener positioned in the fastener driver and ready for deployment.

Detailed Description of the Invention

This Specification discloses various catheter-based devices, systems, and methods for delivering and implanting radially expandable prostheses in the body lumens. For example, the various aspects of the invention have application in procedures requiring the repair of diseased and/or damaged sections of a hollow body organ

and/or blood vessel. The devices, systems, and methods that embody features of the invention are also adaptable for use with systems and surgical techniques that are not necessarily catheter-based.

The devices, systems, and methods are particularly well suited for treating aneurysms of the aorta that primarily occur in the abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation, as well as aneurysms that also occur in the thoracic region between the aortic arch and renal arteries. For this reason, the devices, systems, and methods will be described in this context. Still, it should be appreciated that the disclosed devices, systems, and methods are applicable for use in treating other dysfunctions elsewhere in the body, which are not necessarily aorta-related.

I. OVERVIEW

Fig. 1 depicts a portion of the descending aorta and shows an abdominal aortic aneurysm 20. For the purposes of illustration, Fig. 1 shows the targeted site for delivery and implantation of a prosthesis as being within the abdominal aortic aneurysm 20. It is to be appreciated that the targeted site can also be elsewhere in the body. In the illustrated arrangement, the prosthesis takes the form of an endovascular graft.

In order to provide a consistent orientation for the devices, systems, and methods described herein, the terms proximal or cephalad will be used to describe a relation or orientation toward the head or heart, and the terms distal or caudal will be used to describe a position or orientation toward the feet or away from the heart. Therefore, the devices, systems, and methods can be described as having a proximal or cephalad component and a distal or caudal component. The use of these terms also applies to the implantation apparatus as used in the

implantation process described, i.e., the deployment catheter handle is distal or caudal as the handle of the deployment catheter is oriented toward the feet and away from the heart.

The proximal or cephalad end 202 of a prosthesis deployment catheter 200 can be seen in Fig. 1 positioned over a first guide wire 30 (the guide wire being previously positioned) and extending through at least a portion of the abdominal aortic aneurysm 20. The deployment catheter 200 carries the main body of the prosthesis 120 (see Fig. 2), which is placed at the targeted site, e.g., by radial expansion of the main body prosthesis 120 (see Fig. 3). After expansion of the main body prosthesis 120, one or more fasteners 402 (see Fig. 4) may be introduced by a fastener device 400 to anchor the proximal end 108 of the main body prosthesis, in place.

Fig. 2 depicts the initial stage of the main body prosthesis 120 deployment at the targeted site. While the deployment method can vary, in the illustrated embodiment, the delivery catheter 200 has a movable jacket or outer sheath 210, which overlays the main body prosthesis 120. When the outer jacket 210 is pulled distally, or in a caudal direction, the main body prosthesis 120 is exposed but may remain in an undeployed configuration until releasing means has been activated. Once the releasing means has been activated, the main body prosthesis or a portion(s) of the main body prosthesis 120 is free to radially expand, thereby enlarging to contact at least a portion of the internal walls of the blood vessel. The prosthesis deployment process is continued, including the deployment of one or more lumen extensions, until a multi-lumen or bifurcated prosthesis 100 is fully deployed within the vessel, as can be seen in Fig. 4 and will be described in greater

detail later.

It is to be understood that the terms prosthesis and prostheses both can mean an independent component, or multiple components coupled together, or multiple components not necessarily coupled together. The prosthesis may be either coupled together at or near the targeted site, or exterior the body, or a combination of both.

In a desirable embodiment, the prosthesis is a multi-lumen prosthesis. In an alternative embodiment, the prosthesis is a straight prosthesis. The prosthesis 100 may be self-expanding, or, the prosthesis 100 can utilize an expanding member, such as a balloon or mechanical expander. Fig. 4 depicts a completely deployed multi-lumen or bifurcated prosthesis 100 that is sized and configured to be positioned within the aorta and extend across the aneurysm and into the contralateral iliac artery and the ipsilateral iliac artery. Fig. 5 depicts a completely deployed straight prosthesis 50.

It is to be appreciated that one or more fasteners 402 can be introduced into the multi-lumen prosthesis 100 to anchor the main body 120 and/or lumen extensions 140 in place at different times or at the same time during the procedure.

II. GENERAL METHODS OF ENDOVASCULAR IMPLANTATION

The prosthesis or prostheses 100 as just described lend themselves to implantation in a hollow organ in various ways. The prosthesis may be implanted using catheter-based technology via a peripheral intravascular access site, such as in the femoral artery, optionally with the assistance of image guidance. Image guidance includes but is not limited to fluoroscopy, ultrasound, magnetic resonance, computed tomography, or combinations thereof. Alternatively, the prosthesis can be implanted, e.g., in an open chest surgical procedure.

Figs. 58 to 78 show a representative embodiment of the deployment of a prosthesis of the type shown in Fig. 4 by a percutaneous, catheter-based procedure. Percutaneous vascular access is achieved by conventional methods into the femoral artery, for example.

The implantation of the multi-lumen prosthesis 100 is first described here in a number of general steps. The multi-lumen prosthesis and each of the various tools used to implant the prosthesis are then described with additional detail below. The multi-lumen prosthesis 100 is described in section III and the various implantation apparatus are described in section IV. Additionally, the general implantation steps are then described again with additional detail below in section V.

A first implantation step can be generally described as deploying the main body 120 of the prosthesis. The deployment catheter 200 is positioned within the aortic aneurysm 20 and the main body of the prosthesis is allowed to deploy. Proximal and distal retaining means hold the main body prosthesis in a predetermined relationship to the proximal end 202 of the deployment catheter. By activating a proximal releasing means, the proximal end 108 of the main body prosthesis 120 may be partially or fully released from the deployment catheter shaft so as to allow the proximal stent 130 to expand to contact the aorta or a portion of the aorta. At this step the prosthesis may not be fully released from the deployment catheter. The main body prosthesis 120 may be attached to the deployment catheter 200 through a second proximal retaining means. The proximal end 108 or other areas of the main body prosthesis 120 is fastened to the vessel wall to resist axial migration of the prosthesis.

Next, an extension catheter 350 carrying a first prosthesis lumen extension 140 is guided through the vasculature and to the main body prosthesis 120. The

first lumen extension is telescopically fitted within the second lumen 128 of the main body prosthesis 120 and allowed to radially expand. The extension catheter is then removed, leaving the lumen extension 140 coupled to the main body prosthesis 120 and extending into the contralateral iliac artery.

If the main body prosthesis 120 is attached to the deployment catheter 200 through a second proximal retaining means, a second releasing means is activated to allow the proximal end 108 of the main body prosthesis 120 to release from the deployment catheter shaft 216. The distal releasing means is then activated, allowing the distal end 110 of the main body prosthesis 120 to release from the deployment catheter shaft 216 and radially expand. The deployment catheter 200 is then removed from the body.

Lastly, the extension catheter 350 carrying a second prosthesis lumen extension 140 is guided through the vasculature and to the main body prosthesis 120. The second lumen extension 140 is telescopically fitted within the first lumen 126 of the main body prosthesis and allowed to radially expand. The extension catheter 350 is then removed, leaving the lumen extension 140 coupled to the main body prosthesis 120 and extending into the ipsilateral iliac artery. The multi-lumen prosthesis 100 is now fully deployed across the aortic aneurysm.

III. MULTI-LUMEN PROSTHESIS ASSEMBLY

Fig. 6 shows a multi-lumen prosthesis assembly 100 that embodies features of the invention. In the illustrated embodiment, the multi-lumen prosthesis assembly 100 comprises a main body component 120 and at least one lumen extension 140, desirably two lumen extensions.

The main body component 120 is sized and configured

to fit within a hollow body organ and/or a blood vessel. As described in this Specification, the targeted site of deployment is within the aorta adjacent the renal arteries, as will be described in greater detail later. However, this targeted site of deployment is selected for purposes of illustrating the features of the prosthesis 100, and is not intended to be limiting.

Referring to Fig. 7A, the main body component 120 has a proximal and distal end 108, 110, and includes an interior communicating with a proximal opening 122 for fluid flow into or from the prosthesis. The main body component 120 includes a septum 124 within its interior. The length of the septum 124 within the prosthesis 120 can vary. In the illustrated embodiment, the septum 124 does not extend along the entire length of the main body component 120, but is spaced a distance from the proximal opening 122. In the illustrated arrangement, the septum 124 comprises a longitudinal seam. The seam can be formed by coupling the opposing surfaces together (i.e., the front and back) of the prosthesis material 112 (which is typically a fabric) by sewing, heat bonding, stitching or weaving, for example, or any combination. The coupling of the opposing surfaces together thereby creates a septum or shared, common wall between two lumens, the first lumen 126 and the second lumen 128 (see Figs. 8A and 8B). Typically the seam 124 would be located along the midline of the main body to create two equally sized lumens 126 and 128. However, the location of the seam 124 could be moved, if different sized lumens were desired. In one embodiment shown in Fig. 7C, the septum 124 is formed by a stitch(s) 131 at the septum's proximal end 121, a stitch(s) 133 at the septums distal end 123, and a weave(s) 135 in-between the stitches 131, 133 at the septum's proximal end 121 and distal end 123. The combination of stitches and weaving, for example,

provides added stability to the septum 124.

The septum 124 transforms at least a portion of the interior of the main body component 120 into the multi-lumen flow channel configuration. In the illustrated embodiment, the multi-lumen flow channel configuration comprises dual first and second interior lumens 126 and 128. Due to the septum 124, the dual first and second interior lumens 126 and 128 of the multi-lumen flow channel configuration do not form branched or divergent lumens. The shared common wall or seam (the septum 124) prevents divergence and maintains the lumens 126 and 128 in a non-divergent, generally parallel flow relationship (as Figs. 8A and 8B show).

In the illustrated arrangement, the septum 124 runs generally along the mid-line of the main body component 120, making the multi-lumen flow channel configuration within the main body component 120 essentially symmetric. However, it should be appreciated that the septum 124 could form a non-symmetric multi-lumen flow channel configuration. It should also be appreciated that multiple septums can be present within the interior, transforming the interior of the main body component 120 into several flow lumens. The length of the septum can vary. In a representative embodiment, the septum 124 is typically greater than 10 mm in length and not less than 5 mm in length.

In the illustrated embodiment, the first lumen 126 defines a flow channel sized and configured to reach a targeted destination or source spaced a defined distance from the proximal opening 122, while the truncated second lumen 128 communicates with generally the same targeted destination as the proximal opening 122 of the main body component 120 itself. Furthermore, the septum 124 is sized and configured to accommodate the coupling of a flow channel extension 140 to the first lumen 126 and to

the truncated second lumen 128, to likewise extend their reach to another targeted source or destination spaced from the proximal opening 122, if desired.

The second lumen 128 is truncated along at least a portion of the septum 124. As a result, the distal opening 127 of the first lumen 126 can be said to extend beyond the distal opening 129 of the second lumen 128. Still, the shared common wall (the septum 124) prevents divergence and maintains the lumens 126 and 128 in a non-divergent, generally parallel flow relationship. It is to be appreciated that the first and second lumens 126, 128 may be reversed, i.e., the second lumen 128 may extend beyond the first lumen 126 (see Fig. 7D).

In this arrangement, the multi-lumen prosthesis assembly 100 desirably includes a first and second flow channel lumen extension 140 (see Fig. 6). The first and second lumen extensions 140 desirably comprise the same construction, i.e., they are duplicates of each other. Referring to Fig. 9A, the lumen extension 140 includes a proximal end 142 that is sized and configured to be telescopically fitted within the first lumen 126 and/or the truncated second lumen 128 of the main body component 120. The distal end 144 of the lumen extension 140 is sized and configured to extend the reach of the first lumen 126 and the truncated second lumen 128 to another targeted destination or source spaced a defined distance from the main body component proximal opening 122. As a result, a portion of the extended second lumen 128 is joined to the first lumen 126 by the septum 124, and a portion of the extended second lumen 128 is not joined by the septum 124 to the lumen extension 140 of the first lumen 126.

Both the first lumen 126 and the truncated second lumen 128 of the main body component 120, which is joined by the septum 124 to the first lumen 126, provide an

interface region or socket that is fully enclosed within the body of the main body component 120 itself. The first lumen 126 and the truncated second lumen 128 are therefore not prone to kinking or twisting or other kinds of movement independent of the main body component 120. Passage of a guide wire through the first lumen 126 or the second lumen 128 can occur unimpeded.

Being telescopically fitted within the interface region or socket and enclosed within the main body component 120, the mechanical properties of the lumen extension 140 are supplemented by the structural support and integrity of the main body component 120 itself, and vice versa. Coupled together, the main body component 120 and the lumen extension 140 provide enhanced resistance to migration and/or separation of the lumen extension 140 from the main body component 120. Seated within the enclosed interface region, the lumen extension 140 is peripherally sealed within the main body component 120 to resist leaks or seepage of fluids around the lumen extension 140. The septum 124 can be tapered, curved, wavy, or otherwise non-linear to enhance the connection between the lumen extension 140 and the main body component 120.

In one illustrated use (see Fig. 3), the main body component 120 can be deployed in the aorta in the region of the bifurcation of the first and second iliac, or ipsilateral and contralateral iliac arteries. When the main body prosthesis 120 is deployed, both the first lumen 126 and the second lumen 128 remains in communication with the aorta. After the main body component 120 is deployed, the first lumen extension 140 can be fitted within the distal opening 127 of the first lumen 126, and the second lumen extension 140 can be fitted within the distal opening 129 of the second lumen 128, so that the distal end 144 of the first extension

140 can be sized to reach into the first iliac of the bifurcation, while the distal end 144 of the second extension 140 can reach into the second iliac of the bifurcation (see Fig. 4). In this arrangement, the first lumen extension 140 of lumen 126 serves as a first lumen or ipsilateral lumen of the prosthesis 100, and the lumen extension 140 of the second lumen 128 serves as a second lumen or contralateral lumen.

The main body component 120 may include a proximal sealing stent 130 at its proximal end 108, which may extend beyond the prosthetic material 112 (see Fig. 7A). The proximal stent 130 orients the main body prosthesis 120 within the lumen and aids in maintaining the position of the main body prosthesis 120 in the aorta without obstructing the normal blood flow into the renal arteries. The proximal sealing stent 130 may also serve to limit the length of the prosthesis edge which is exposed to the flow of fluids and may cause scalloping. The proximal sealing stent 130 may be a self-expanding zigzag or diamond shaped stent, for example, and is desirably sewn inside the prosthesis material 112, although the stent may be outside, or may be wrapped between two layers of prosthesis material 112, for example.

Typically, this region of the aorta (proximal neck of the aneurysm just below the renal arteries) is also one area where one or more fasteners 402 may be introduced by a fastener device 400 to anchor the prosthesis 100 in place (see Fig. 4). However, it should be noted that other areas throughout the main body 120 and lumen extensions 140 can also be fastened in place. It is desirable that this region of the main body component 120 be sized and configured for the receipt and retention of fasteners, e.g., the size and spacing of diamond or zigzag stent patterns to specially accommodate

the placement of fasteners; and/or the use of woven fibers with an "X-pattern" or a "sinusoidal pattern" to specially accommodate placement of fasteners; and/or to fold over the prosthetic material 112 to form multiple layers, to reinforce the prosthesis in the region where fasteners 402 are placed; and/or the use of denser weave patters or stronger fibers from, e.g., Kevlar™ material or Vectran™ material or metallic wire woven alone or interwoven with typical polyester fibers in the region were fasteners are placed. It may also be desirable to fluoroscopically indicate this region of the prosthesis with radiopaque markers 132 on the prosthetic material 112 or proximal sealing stents 130 to aid in positioning the fastening devices.

Additional stents may be utilized throughout the main body component 120. Desirably, a minimal number of stents would be utilized within the main body component 120.

The multiple lumens 126 and 128 in the main body component 120 may typically be supported with distal stent rings 134 sewn or otherwise attached to the inside or outside of the prosthetic material 112. The proximal apices 136 of the stent rings 134 desirably are angled or curved inwardly (see Fig. 7B). The inward angle provides a retentive feature when the lumen extension 140 is positioned within a first or second lumen (see Fig. 10B). Alternative retentive features may also be used, such as hooks, barbs, loops of fabric or loops/folds of graft material or pockets in graft material, for example. Ideally, the distal stent rings 134 in one lumen 126 are staggered axially in position with the stent rings 134 in the other lumen 128, so that they do not overlap each other when the main body component 120 is radially compressed prior to deployment.

Rotational orientation of the main body component

120 within the vessel lumen or hollow body organ is accomplished with additional radiopaque markers 137 and 138 attached to the main body prosthesis 120 for visualization under fluoroscopy. Typically, these markers may be attached to the prosthetic material 112. Still, the markers 137 and 138 may be attached to the proximal sealing stent 130 or distal stent rings 134 instead of or in addition to the prosthetic material 112 to help fluoroscopically determine the location of all prosthesis openings. The radiopaque markers typically are in the form of marker bands, tight wound coils, or wire made from radiopaque materials such as platinum, platinum/iridium, tantalum, or gold for example.

Desirably, one or more markers 137, 138, are longer than the other, and are attached on opposite sides of the main body component 120 with the longer markers 137 aligned on the side with the first lumen 126 and the shorter markers 138 aligned on the side with the second lumen 128, for example. In an alternative embodiment the markers could be aligned with the septum. The markers 137 and 138 enable the clinician to determine the desired rotational orientation of the main body prosthesis 120 in the delivery system so that, upon deployment, the first distal opening 127 and the second distal opening 128 are aligned with the desired iliac arteries. The proximal markers 132 may also be included to enable the clinician to determine the position of the proximal end 108 of the main body component 120 in relation to the fixation point of the aorta. Additionally, distal markers 139 may be included to aid in the location of the distal openings 127, 129, and the insertion of the lumen extension 140. Insertion depth marker(s) 125 may be attached near the septum 124, or may be attached to the septum, or may be attached to the prosthesis material 112, for example, to indicate the location of and insertion depth for the

lumen extension 140.

As previously described, the main body 120 (and the lumen extension 140) desirably utilizes a prosthetic material 112. The material 112 of the main body 120 may carry individual self-expanding, zigzag or diamond type stent rings, for example. The stent rings need not be attached to one another throughout the main body prosthesis 120. However, it may be desirable in certain locations within the prosthesis structure 120 to have attachments between the individual stent rings to provide stability and/or additional radial support.

As previously stated, the septum 124 is formed by sewing, heat bonding, stitching, or weaving opposing surfaces (i.e., the front and back) of the prosthetic material 112 of the main body component 120 together. In the region of the septum 124, the stent rings 134 extend from the septum 124 about the formed lumen, but do not enter or otherwise interrupt the septum 124 itself. The septum 124 is continuous and is formed separate from the supporting structure of stent rings 134.

The individual distal stent rings 134 allow for longitudinal main body prosthesis 120 compliance while maintaining radial support of the prosthesis lumens. This technical feature allows the prosthesis to more readily accommodate changes in vessel/aneurysm morphology.

The stents can be made, e.g., from Nitinol®. Still, other materials, manufacturing methods and designs can be used. Each of the stents may be sewn onto prosthetic material 112. In certain locations it is desired to have the stents attached to the outer diameter of the prosthetic material 112. Still, it is also contemplated that the stents could be attached to the inner diameter of the prosthetic material 112.

In the illustrated embodiment, the prosthetic material 112 is woven polyester, and the attachment of

the stents is made with polyester suture. However, it is also contemplated that other attachment means could be utilized to secure the stents to the prosthetic material 112. These means include bonding; capturing the stents between two layers of prosthetic material 112; and incorporating the stents directly into the woven prosthetic material 112.

As seen in Fig. 9A, the lumen extension 140 has at least one spiral stent 146 positioned along at least a portion of the length of the extension and attached to the outside of prosthetic material 112 to provide stability and/or additional radial support. However, as in the main body component 120, it is contemplated that the stent 146 could also be placed on the inside of the prosthetic material 112, or the spiral stent 146 could be captured between two layers of prosthetic material (not shown). The prosthetic layer 112 could be a continuous tube or non-tubular. The prosthetic material 112 could cover the entire lumen extension 140 or the prosthetic material 112 could cover only a portion of the lumen extension. Furthermore, as previously discussed, the spiral stent 146 need not be one continuous stent along the length of the extension. The addition of the spiral stent 146 to the lumen extension 140 aids in the deployment of the lumen extension and allows for longitudinal compliance while maintaining radial support of the lumen within the lumen extension 140. Typically, radiopaque extension markers 148 are used on each end of the extension 140 to aid in the visualization of the placement of the lumen extension 140 within the lumen of the first distal opening 127 and the second distal opening 129 of the main body component 120.

As shown in Figs. 9A through 9D, the engaging stent or stents 150 in the lumen extension 140 can be sized, configured, and arranged to engage the stent rings 134 in

the first lumen 126 and the second lumen 128 of the main body 120. The distal apices 147 of at least one engaging stent 150 are angled outwardly to engage the mating distal stent 134 on the main body component 120 (seen particularly in Figs. 9B and 9D). This engagement prevents the lumen extension 140 from moving or migrating axially in relation to the first lumen 126 and the second lumen 128 after the lumen extension 140 has been deployed. In an alternative embodiment shown in Figs. 10A through 10D, the spiral stents 146, which are attached to the outside of the lumen extension 140, may engage with the distal stents 134 of the main body 120 without being angled outwardly. In either of these embodiments, additional features may be included with the main body 120 or the lumen extensions 140 to help prevent the lumen extension 140 from moving or migrating axially in relation to the main body 120, such as hooks, barbs, loops of fabric or loops/folds of graft material, or pockets in graft material, for example.

During use (see Fig. 58), the deployment catheter 200 is navigated over the guide wire 30 through an iliac to the desired location within the aorta near the renal arteries. The catheter 200 carries the main body component 120 of the multi-lumen prosthesis system 100 in a radially reduced configuration. At the targeted site, the retaining jacket 210 is retracted which allows the distal stent 134 of the second lumen 128 to radially expand into the position shown in Fig. 60. The distal stent 134 of the first lumen 126 and the proximal stent 130 are not allowed to expand until releasing means have been activated.

As Figs. 69 and 70 show, the first lumen extension 140 is carried in a radially compressed condition by an over-the-wire extension catheter 350 coming from the contralateral iliac, for example. The catheter 350

deploys the first lumen extension 140, such that the proximal end 142 of the lumen extension 140 is telescopically received within the second lumen 128 of the main body component 120 and the distal end 144 extends into the contralateral iliac, as Fig. 71 shows. The second lumen extension 140 is then carried in a radially compressed condition by the extension catheter 350 coming from the ipsilateral iliac, for example. The extension catheter 350 deploys the second lumen extension 140, such that the proximal end 142 of the lumen extension 140 is telescopically received within the first lumen 126 of the main body component 120 and the distal end 144 extends into the ipsilateral iliac, as Fig. 77 shows. Only when each lumen extension 140 is telescopically received within the first lumen 126 and second lumen 128 of the main body component 120, a bifurcated prosthesis 100 is formed with divergent lumens, as seen in Fig. 78.

IV. IMPLANTATION APPARATUS

A. Prosthesis Deployment Catheter

Fig. 11 shows a prosthesis deployment catheter 200 having features of the invention. The purpose of the catheter 200 is to (i) contain and/or restrain the main body prosthesis 120 prior to its deployment (see Fig. 14A), (ii) deliver the main body prosthesis 120 through the vasculature to a desired location within the body, e.g., a hollow body organ or a blood vessel (see Fig. 1), and (iii) controllably deploy the main body prosthesis 120 in the desired location (see Figs. 2 and 3), including maintaining a stable position of the main body prosthesis 120 in a partially deployed condition while the main body prosthesis is fastened to the vessel wall. In the illustrated embodiment, the proximal end 202 of the catheter 200 is shown positioned over a guide wire 30 in a body lumen (see Fig. 1). The catheter 200 carries

the main body prosthesis 120 in a radially reduced configuration to the targeted site. At the targeted site, the catheter 200 releases the radially reduced prosthesis 120, which expands radially (see Figs. 2 and 3). After partial or complete expansion or deployment of the main body prosthesis 120, one or more fasteners 402 are desirably introduced by a fastener device 400 to anchor the main body prosthesis 120 in place. The fasteners 402 may also serve to provide apposition of the prosthesis material 112 to the hollow body organ or vessel wall and to seal and/or repair a fluid leak. Further details of the fastener device and fastener can be found in section three (3) below.

As previously described, the prosthesis 100 can be sized and configured to be either straight or bifurcated form. Fig. 4 depicts a completely deployed bifurcated prosthesis 100. Fig. 5 depicts a completely deployed straight prosthesis 50.

For the purposes of illustration, Fig. 1 shows the targeted site as being within an abdominal aortic aneurysm. Of course, the targeted site can be elsewhere in the body.

As shown in Figs. 11 through 14B, the catheter 200 comprises an inner assembly 208, an outer jacket 210, and a handle assembly 212. These components will now be individually described in greater detail.

1. The Inner Assembly

In the illustrated embodiment (see Figs. 12 through 14B), the inner assembly 208 comprises a central shaft 216, which functions as a carrier for the main body prosthesis 120, proximal and distal retaining means 218, 220, and a catheter tip component 222. The proximal retaining means 218 desirably comprises a first proximal retaining means 224 and a second proximal retaining means 226. The first proximal retaining means 224 desirably

retains at least a portion of the main body prosthesis 120 in a radially compressed, and/or partially radially expanded condition prior to deployment and prior to fastening the main body prosthesis 120 to the vessel wall. The second proximal retaining means 226 desirably functions to stabilize the deployed proximal sealing stent 130 by preventing longitudinal and to a limited extent rotational movement. Each of the first and second proximal retaining means also desirably include a co-acting releasing means or mechanism 228, 230 for maintaining the first or second proximal retaining means 224, 226 in a desired relationship with the main body prosthesis 120 prior to activation. The distal retaining means or mechanism 220 also desirably includes a releasing means or mechanism 232 for activating/releasing the distal retaining means or mechanism 220. The releasing means may comprise a wide variety of devices, such as wire or wires, sutures, magnetics, or fluids, and may include sliding, pulling or pushing, for example.

a. The Central Shaft

In the embodiment shown in Figs. 13 and 14A, the central shaft 216 and the proximal and distal retaining means 218, 220 are located within the confines of the outer jacket 210. In this respect, the outer jacket 210 functions as an enclosure for the main body prosthesis 120 on the carrier (see Fig. 14A). In this arrangement, the catheter tip component 222 is attached to the proximal end of the central shaft 216, and the proximal end of the outer jacket 210 terminates adjacent the catheter tip component 222. Thus, the catheter tip component 222 extends outward beyond the outer jacket 210. The central shaft 216, the proximal and distal releasing means 228, 230, 232, and the outer jacket 210 may be coupled to the handle assembly 212 at the proximal end of the catheter handle assembly 212 (see Fig. 11). As

can be seen in Fig. 14A, the main body prosthesis 120 is contained in a cavity 234 defined between the central shaft 216 and the outer jacket 210 in the proximal section of the deployment catheter 200.

The central shaft 216 extends from the handle assembly 212 to the catheter tip component 222. The central shaft 216 may be made, e.g., from stainless steel or other suitable medical materials including other metals or polymers. The central shaft 216 comprises at least one lumen, desirably more than one lumen, and more desirably four lumens.

One lumen may be described as the central lumen 236 (see Fig. 15), with an inner diameter between .010 and .120 inches, desirably between .020 and .060 inches and most desirably between .030 and .050 inches. As described, the central lumen 236 allows for the insertion of the guide wire 30 up to 0.038″ diameter. The catheter tip component 222 also desirably has at least one lumen 238 (see Fig. 16) configured to align with at least one lumen within the central shaft 216. This lumen 238 allows for the insertion of the guide wire 30 through the central shaft 216 and through the catheter tip component 222. Typically this lumen 238 will have an inner diameter between .010 and .120 inches, desirably between .020 and .060 inches and most desirably between .030 and .050 inches.

b. Catheter Tip

Desirably, the catheter tip component 222 is flexible and has a long, tapered proximal end 240 and a shorter, tapered distal end 242. The maximum diameter of the catheter tip component 222 is approximately the same as the outside diameter of the proximal end of the outer jacket 210. The proximal end 240 of the catheter tip component 222 provides a smooth tapered transition from the lumen 238 containing the guide wire 30 to the

proximal edge of the outer jacket 210. This feature aids in catheter insertion and navigation through tortuous anatomy over the guide wire 30. The tapered section on the distal end 242 of the catheter tip component 222 prevents the catheter tip component 222 from inadvertently engaging the main body prosthesis 120, portions of the surrounding anatomy, or an introducer sheath or the like during removal of the deployment catheter 200 from the body.

2. Proximal Retaining Means

a. First Proximal Retaining Means

As can be seen in Figs. 17 through 19, in the illustrated embodiment, the first proximal retaining means 224 comprises at least one suture, or sutures, 252 and/or equivalent structures, which are coupled to the prosthetic material 112, or one or more stents 130 on the main body prosthesis 120. The suture 252 is, in turn, looped around the releasing means 228, e.g., a release wire 250, when the release wire 250 is in its proximal-most position, as Figs. 17 and 18A shows. Distal retraction of the wire 250 withdraws the wire 250 from the suture loop 252, and allows the proximal end 108 of the main body prosthesis 120 to radially expand, as Fig. 19 shows. In an alternative embodiment, the suture 252 may comprise more than one suture, i.e., two or more suture loops. Fig. 18B shows the path of two suture loops 252 looped around the release wire 250.

Belt loops or the like may be provided on the main body prosthesis 120 and/or lumen extensions 140 to guide and support the suture loop(s) along the path of the suture loop (see Figs. 17 and 46B for example). The belt loops can be spaced at desired circumferential intervals, such as every ninety degrees, for example.

In the illustrated embodiment, one end of the suture loop 252 is coupled to the prosthetic material 112 or one

or more stents 130 at or near the proximal end 108 of the main body prosthesis 120. The suture loop 252 is then looped around the main body prosthesis 120 and the releasing means 228 in a predetermined pattern, as shown in Fig. 18A, in order to compress and retain the proximal end 108 of the prosthesis 120. The free end of the suture loop 252 is then coupled to the prosthetic material 112 or one or more stents 130 at or near the proximal end 108 of the main body prosthesis 120. Fig. 18B shows two separate loops 252 looped around the main body prosthesis 120 and the release wire 250. It should be appreciated, however, that suture loop 252 could be coupled to stents elsewhere in the main body prosthesis 120, and/or the other components of the main body prosthesis 120 as well.

The suture loop 252 and releasing means 228, e.g., release wire 250, of the embodiment just described retains the prosthesis 120 in a desired relationship to the central shaft (see Fig. 17). The suture loop 252 and the releasing means 228 help to keep the main body prosthesis 120 from moving distally as the outer jacket 210 is retracted. The suture loop 252 also keeps the stent or stents 130 that are retained by the suture loop 252 in a radially compressed condition as the outer jacket 210 is retracted. The suture loop 252 and releasing means 228 prevent the proximal end 108 of the main body prosthesis 120 from self-expanding until the releasing means 228 has been withdrawn. In the illustrated embodiment, the withdrawal of the releasing means 228 is accomplished by operating a control knob to move the releasing means 228 distally, withdrawing the releasing means 228 away from the suture loop 252. Once the releasing means 228 is withdrawn, the restrained components of the main body prosthesis 120 are free to self expand, as Fig. 19 shows.

As can be seen in Figs. 20 and 21, the first

proximal releasing means 228 comprises a first proximal release hub 244 positioned over the central shaft 216, and a release wire 250. The first proximal release hub 244 may include a small hole or lumen 246 in the proximal end of the hub 244 that is in fluid communication with a first proximal release lumen 248 within the central shaft 216. Each lumen 246, 248 desirably includes a diameter sufficiently large to accommodate the first proximal release wire 250 extending from the handle assembly 212 to beyond the first proximal release hub 244. It is to be appreciated that the release wire 250 may extend external the shaft 216 as well.

The first proximal retaining means 224 holds the main body prosthesis 120 in a desired configuration prior to deployment (see Figs. 17 and 18A) and the first proximal releasing means 228 selectively releases the main body prosthesis 120 for the first stage of deployment (see Fig. 19). In the illustrated embodiment, the distal end of the first proximal release wire 250 is connected to an actuator or control button or knob in the handle assembly 212, as will be described further below.

The main body prosthesis 120 is retained by at least the first proximal retaining means 224 along the central shaft 216 in the cavity 234, which extends between the distal end 242 of the catheter tip component 222 and the proximal end of a spacer 206 (as best seen in Fig. 14A). In the illustrated embodiment, the releasing means 228 includes the release wire 250 that may extend through at least a portion of the central shaft 216. The proximal end of the wire 250 passes through the lumen 246 of the first proximal release hub 244. The first proximal release wire 250 is thereby kept in a desired relationship within or along the central shaft 216. The distal end of the first proximal release wire 250 is coupled to the control knob, such that fore and aft

movement of the knob moves the release wire 250, respectively, proximally and distally.

As illustrated and described, the first proximal releasing means 228 is coupled to one restrained component of the main body prosthesis 120, i.e., suture loop 252. It should be appreciated, however, that the releasing means 228 can be coupled to the main body prosthesis 120 at two or more restrained regions, so that withdrawal of the releasing means 228 frees the prosthesis at two or more restrained regions. It should also be appreciated that the releasing means 228 can comprise more than a single releasing element. For example, multiple, individual releasing wires 250 could be coupled to the main body prosthesis 120 at different regions, so that release of separate regions of the main body prosthesis 120 can be individually controlled.

b Second Proximal Retaining Means

Referring back to Fig. 12, the proximal retaining means 218 may also incorporate a second retaining means 226 which may function in cooperation with, or separate from the first proximal retaining means 224. The second proximal retaining means 226 may be held in place by the second proximal releasing means 230 in a predetermined, spaced relationship with the central shaft 216.

Referring now to Figs. 22 through 27, the second proximal retaining means 226 may comprise at least one stabilizing arm 256, and/or equivalent structures, and desirably more than one stabilizing arm, such as three stabilizing arms, as shown. The second proximal releasing means 226 may comprise a second proximal release hub 266 and a second proximal release wire or wires 268.

The distal ends 258 of the stabilizing arms 256 are coupled to the second proximal release hub 266. In a pre-deployment configuration, the proximal ends 262 of the stabilizing arms 256 are arched back generally toward the

first proximal release hub 244 (see Figs. 23 and 24) and are releasably attached to the prosthesis material 112 at or near the proximal end 108 of the main body prosthesis 120 (see Figs. 24 and 25). In a post-deployment configuration, as seen in Fig. 26, the stabilizing arms 256 extend proximally toward the catheter tip 222.

The proximal ends 262 of the stabilizing arms 256 include a stabilizing arm aperture 264. In the pre-deployment configuration, the stabilizing arms 256 are positioned within the proximal opening 122 of the main body prosthesis 120 and the second proximal release wire 268 is stitched or otherwise extended through the stabilizing arm aperture 264 and through the prosthesis material 112, releasably securing the stabilizing arms 256 to the main body prosthesis 120 (as best seen in Fig. 25). Distal retraction of the second proximal release wire 268 (using a second control knob, to be described later) withdraws the second proximal release wire 268 from the prosthesis material 112 and releases the stabilizing arms 264. The main body prosthesis 120 is now free from the retentive feature of the stabilizing arms 256, and the stabilizing arms return to the post-deployment configuration, as shown in Fig. 26. It is to be appreciated that the second proximal release wire 268 may comprise multiple release wires, including one release wire for each stabilizing arm 256. The second proximal release wire 268 may comprise a single wire extending through the central shaft, and then divide into multiple wires to individually engage the stabilizing arms, or the release wire 268 may comprise multiple wires extending through the central shaft 216 to individually engage each stabilizing arm 256. In an alternative embodiment, the stabilizing arms 256 could be positioned in the reverse orientation on the catheter central shaft 216. Stabilizing arms of this configuration would be

biased open away from the central shaft 216 and would require a secondary means to retain them in close proximity to the central shaft 216 in order to be rejacketed before catheter removal.

In the embodiment shown in Figs. 24 through 27, the second proximal retaining means 226 includes a second proximal release hub 266 positioned over the central shaft 216. The second proximal release hub 266 may include a small hole or lumen 270 in the proximal end of the hub 266 that is in fluid communication with the second proximal release lumen 272 within the central shaft (see Figs. 24 and 27). The lumen 270 and 272 desirably includes a diameter sufficiently large to accommodate at least one second proximal release wire 268 extending from the handle portion 212 to beyond the second proximal release hub 266. It is to be appreciated that the release wire 268 may extend external the shaft 216 as well.

The second proximal retaining means 226 holds the main body prosthesis 120 in a desired configuration prior to deployment (see Figs. 19 and 24) and selectively releases the main body prosthesis 120 for the second stage of deployment (see Fig. 26). In the illustrated embodiment, the distal end of the second proximal release wire 268 is connected to an actuator or control button or knob in the handle assembly 212, as will be discussed further below.

The main body prosthesis 120 is retained by the second proximal retaining means 226 in a spaced apart relationship to the central shaft 216 (see Fig. 24). In the illustrated embodiment, the second proximal releasing means 230 includes the second proximal release wire 268 that may extend through at least a portion of the central shaft 216. The proximal end of the release wire 268 passes through the lumen 270 of the second proximal

release hub 266. The second proximal release wire 268 is thereby kept in a desired relationship within or along the central shaft 216. The distal end of the second proximal release wire 268 is coupled to the second control knob, such that fore and aft movement of the second knob moves the second proximal release wire 268, respectively, proximally and distally.

3. Distal Retaining Means

As can be seen in Figs. 28 through 33, in the illustrated embodiment, the distal retaining means 220 comprises at least one suture, or sutures, 274 and/or equivalent structures, which are coupled to the prosthetic material 112, or one or more stents 134 on the main body prosthesis 120. Desirably, the suture 274 is coupled to the prosthesis material 112 near the distal end 110 of the main body 120, and more desirably near the distal opening 127 of the first lumen 126. The suture 274 is, in turn, looped around the releasing means 232, e.g., a release wire 282, when the release wire 282 is in its proximal-most position, as Figs. 28 and 29A show. Distal retraction of the wire 282 withdraws the wire 282 from the suture loop 274, and allows the distal end 110 of the main body prosthesis 120 to radially expand, as Fig. 30 shows. In an alternative embodiment, the suture 274 may comprise more than one suture, i.e., two or more suture loops. Fig. 29B shows the path of two suture loops 252 looped around the release wire 292.

As described for the first proximal retaining means, belt loops or the like may be provided on the main body prosthesis 120 and/or lumen extensions 140 to guide and support the suture loop(s) along the path of the suture loop. The belt loops can be spaced at desired circumferential intervals, such as every ninety degrees, for example.

In the illustrated embodiment, one end of the suture

loop 274 is coupled to the prosthetic material 112 or one or more stents 134 at or near the distal end 110 of the main body prosthesis 120. The suture loop 274 is then looped around the main body prosthesis 120 and the distal releasing means 232 in a predetermined pattern, as shown in Fig. 29A, in order to compress and retain the distal end 110 of the main body prosthesis 120. The free end of the suture loop 274 is then coupled to the prosthetic material 112 or one or more stents 134 at or near the proximal end 110 of the main body prosthesis 120. Fig. 29B shows two separate loops 252 looped around the main body prosthesis 120 and the release wire 250. It should be appreciated, however, that suture loop 274 could be coupled to stents elsewhere in the main body prosthesis 120, and/or the other components of the main body prosthesis 120 as well.

The suture loop 274 and releasing means 232, e.g., release wire 282, of the embodiment just described retain the distal end of the main body prosthesis 120 to the central shaft 216 (see Fig. 28). The suture loop 274 and the releasing means 232 keep the main body prosthesis 120 from moving distally as the outer jacket 210 is retracted. The releasing means 232 also keeps the stent or stents 134 that are retained by the suture loops 274 in a radially compressed condition as the outer jacket 210 is retracted. The suture loop 274 and releasing means 232 prevent the distal end 110 of the main body prosthesis 120 from self-expanding until the releasing means 232 has been withdrawn. In the illustrated embodiment, the withdrawal of the releasing means 232 is accomplished by operating a control knob to move the releasing means 232 distally, withdrawing the releasing means 232 and away from the suture loop 252. Once the releasing means 232 is withdrawn, the restrained components of the main body prosthesis 120 are free to

self expand, as Fig. 30 shows.

In the embodiment shown in Figs. 28 through 31, the distal releasing means 232 includes a distal release hub 276 positioned over the central shaft 216 and a release wire 282. The distal release hub may include a small hole or lumen 278 in the proximal end of the hub that is in fluid communication with a distal release lumen 280 within the central shaft 216 (see Fig. 31). Each lumen 278, 280 desirably includes a diameter sufficiently large to accommodate a distal release wire 282 extending from the handle assembly 212 to beyond the distal release hub. It is to be appreciated that the release wire 282 may extend external to the shaft 216 as well.

The distal retaining means 220 holds the distal end 110 of the main body prosthesis 120 in a desired configuration prior to deployment of the distal end (see Fig. 28) and the distal releasing means 232 selectively releases the distal end 110 of the main body prosthesis 120 for the final stage of deployment (see Fig. 30). In the illustrated embodiment, the distal end of the distal releasing means 232 is connected to an actuator or control button or knob in the handle assembly 212, as will be described further below.

In the illustrated embodiment, the distal releasing means 232 includes the distal release wire 282 that may extend through at least a portion of the central shaft 216. The proximal end of the wire 282 passes through the lumen 278 of the distal release hub 276. The proximal end of the distal release wire 282 then may extend back into the central shaft 216 through the second distal release hole or lumen 284 positioned spaced apart from the distal release hub 276. The proximal end of the release wire 282 is thereby kept in a desired relationship within or along the central shaft 216. The distal end of the distal release wire 282 is coupled to the distal control knob,

such that fore and aft movement of the distal control knob moves the distal release wire 282, respectively, distally and proximally.

As illustrated and described, the distal releasing means 232 is coupled to the main body prosthesis 120 or a component of the main body prosthesis, i.e., suture loop 274. It should be appreciated, however, that the distal releasing means 232 can be coupled to the main body prosthesis 120 at two or more restrained regions, so that withdrawal of the distal releasing means 232 frees the prosthesis at two or more restrained regions. It should also be appreciated that the distal releasing means 232 can comprise more than a single releasing element. For example, multiple, individual releasing wires 282 could be coupled to the main body prosthesis 120 at different regions, so that release of separate regions of the distal end of the main body prosthesis 120 can be individually controlled.

In an alternative embodiment, the distal retaining means 220 may comprise the prosthesis material 112. As can be seen in Fig. 32, the distal release wire 282 may be threaded through the prosthesis material 112 near the distal end 110 of the main body prosthesis 120, e.g., the first lumen 126. The distal release wire 282 then desirably extends into the second distal lumen 284. The proximal end of the release wire 282 is thereby kept in a desired relationship within or along the central shaft 216 to retain the wire 282. In this configuration, the distal stent(s) 134 are not radially restrained. As the outer jacket is retracted, the distal end 110 of the main body prosthesis 120 is free to radially expand. The distal release wire 282 serves to maintain the position of the distal end 110 relative to the catheter shaft 216. This feature allows for a greater flow of fluid through the lumens of the main body prosthesis while still

maintaining longitudinal or axial control of the main body prosthesis 120 during the deployment process. In the illustrated embodiment, the withdrawal of the release wire 282 is accomplished by operating a control knob to move the release wire 282 distally, withdrawing the release wire 282 from the prosthesis material 112 and releasing the restrained components of the main body prosthesis 120 from the catheter shaft 216, as Fig. 33 shows.

B. The Outer Jacket

As previously described, the outer jacket 210 serves to restrain the stents 130, 134 on the main body prosthesis 120 from expanding and allows for a controlled deployment of the main body prosthesis 120 within the body (see Fig. 14A). In the illustrated arrangement, the outer jacket 210 is coupled to an actuator or knob 302 on the handle assembly 212, as will be described in greater detail below.

As Fig. 14A shows, the outer jacket 210 extends proximally over the spacer 206 and main body prosthesis 120 and terminates adjacent the distal end 242 of the catheter tip component 222. Typically, the outer jacket 210 can be made of a polymer tube or similar materials known in the art. In one embodiment, the jacket 210 may be free of structural reinforcement. In an alternative embodiment (shown in Fig. 14B), the jacket 210 may include structural reinforcement, such as but not limited to, a wire or rod 211 positioned longitudinally along a length of the jacket, and/or a wire or rod 213 positioned helically around a length of the jacket. The structural reinforcement may also be in the form of a coil(s) or braided wire, for example. The plasticity of the structural reinforcement may be altered to affect the flexibility of the jacket 210 depending on a selected application. In addition, the structural reinforcement

may extend along the full length of the jacket 210, or may be positioned along only a portion or portions of the length of the jacket. The structural reinforcement may be embedded within the jacket 210, or may be coupled to the interior or exterior surface of the jacket.

In the illustrated embodiment, the outer jacket 210 is configured to maintain a consistent diameter throughout its entire length (see Fig. 11). The outer jacket may also be tapered due to a difference in outer diameters of the catheter tip component 222. The diameter of the outer jacket 210 is intended to contain the main body prosthesis 120, and optionally an extension portion 140 or portions of the main body prosthesis 120, if present. The outer diameter continues distally to the handle assembly 212. The relatively small size of the outer diameter of the outer jacket 210 also allows for better blood circulation passed the deployment catheter 200.

Returning to Fig. 14A, the spacer 206 provides support for the outer jacket 210 and, by occupying space within the outer jacket 210, reduces the amount of air entrapped within the deployment catheter 200. The proximal end of the spacer 206 desirably terminates adjacent the distal end 110 of the main body prosthesis 120. In this arrangement, the cavity 234 containing the main body prosthesis 120 extends from the distal end 242 of the catheter tip component 222 to the proximal end of the spacer 206. As Fig. 14A shows, the spacer 206 is positioned over the central shaft 216 and the distal end of the spacer 206 is connected to the handle assembly 212. Typically, the spacer 206 can have an outer diameter slightly less than the inner diameter of the outer jacket 210. The spacer 206 can comprise a single lumen or an array of multiple lumens for passage of the various components within the spacer 206.

C. Handle Assembly

The handle assembly 212 provides the operator with longitudinal or axial control and rotational control of the deployment catheter 200 within the body and provides access to the actuator(s) or control means for deploying the main body prosthesis 120.

Referring to Figs. 34 through 36, the handle assembly 212 comprises a handle body 290, a jacket retraction means 292, which is connected to the distal end of the outer jacket 210, a sliding knob 294 which may also be connected to the distal end of the outer jacket 210, and at least one actuator or knob which is attached to the distal end of the proximal and distal releasing means. Desirably, the handle 212 comprises a separate knob for each of the first proximal releasing means 228, the second proximal releasing means 230, and the distal releasing means 232.

In the illustrated embodiment, the central shaft 216 is captured within the handle 212 and has a guide wire receiving luer 296 and an infusion valve 297 coupled to its distal end, which is located at the distal end of the handle assembly 212 (see Figs. 37 and 38). This feature prevents the position of the main body prosthesis 120 from moving relative to the handle body 212 while the outer jacket 210 is retracted, and allows for irrigation or flushing of the catheter shaft 216, such as with a saline solution.

To withdraw the outer jacket 210 from the catheter tip 222 and expose the proximal end of the main body prosthesis 120 (see Figs. 37 through 40), the jacket retraction means 292 is used. The jacket retraction means 292 may include a variety of different mechanisms to selectively control the retraction of the jacket 210 from the catheter tip 222. In the illustrated embodiment, the jacket retraction means 292 comprises a rack and pinion

type control mechanism to provide a mechanical advantage sufficient to withdraw the jacket 210 from the catheter tip 222. A pinion 298 is carried by a gear axle 300, and is rotated by a starting knob 302 positioned on at least one end of the gear axle 300, as best seen in Fig. 41. A single starting knob may be present, or as shown in Figs. 39 and 40, two co-acting starting knobs 302 may be available for the clinician, one positioned on a first side 304 and one positioned on a second side 306 of the handle 212. A complimentary rack 308 is carried by a jacket slide 310. The pinion 298 controls distal movement of the rack 308 along the jacket slide 310 between a first (jacket extended) position 312, shown in Fig. 39, and a second (jacket retracted) position 314, shown in Fig. 40.

The jacket slide 310 is coupled to the jacket 210 and is temporarily coupled to the gear rack 308 via a spring loaded connecting pin 316. The connecting pin 316 disengages the jacket slide 310 at a predetermined position in the handle body 290 by springing or otherwise retracting into a recess 318 in the handle body 290. When the connecting pin 316 disengages, the jacket slide 310 is free to travel in both a proximal and distal direction without re-engaging the rack 308. The rack 308 desirably remains in this retracted position 314. A ratchet pawl, such as a spring backed ratchet pawl 320 may be coupled to the rack 308 to allow the rack to travel in a distal direction, but restrict proximal travel of the rack 308. Ratchet teeth 322 may be provided in the handle body 290 to engage the ratchet pawl 320.

Once the jacket slide 310 has traveled distally and the rack 308 has been disengaged, the jacket sliding knob 294 may then be used to continue the retraction of the jacket 210 from the main body prosthesis 120. The jacket slide 310 is moved distally until the outer jacket 210 is

free of the main body prosthesis 120 (see Fig. 60, for example). The portion or portions of the main body prosthesis 120 that are not coupled to the proximal and distal retaining means 218, 220, are free to self-expand, as Fig. 60 shows. However, the portions of the main body prosthesis 120 that are coupled to the proximal and distal retaining means 218, 220, are still restrained from self-expansion, despite withdrawal of the outer jacket 210, as Fig. 60 also shows. The stent structure of the main body prosthesis 120 is thereby kept restrained in a close relationship against the central shaft 216 while the outer jacket 210 is retracted. The proximal and distal retaining means 218, 220 prevents the main body prosthesis 120 from moving relative to the central shaft 216 during retraction of the outer jacket 210, which potentially minimizes blood flow through the main body prosthesis 120 during the deployment process. Furthermore, as described, the main body prosthesis 120 is not "pushed out" of the catheter. The main body prosthesis 120 therefore need not have longitudinal stiffness or a stent structure with a "spine".

To employ the first proximal retaining means 224, the first proximal sliding knob 322 (see Fig. 34) is moved distally until the proximal end of the first proximal releasing means 228 is withdrawn from the first proximal retaining means 224, as previously described. In the illustrated embodiment, the first proximal release wire 250 is positioned within the loops of the suture loop 252, as seen in Figs. 17 and 18A. As the first proximal release wire 250 is withdrawn from the suture loop 252, the suture loop 252 releases its retentive feature, yet may remain coupled to the prosthesis material 112. The proximal end 108 of the main body prosthesis 120 is thereby free to self-expand to its first stage deployment configuration, as Fig. 19 shows.

The same process is repeated for the second proximal retaining means 226 and the distal retaining means 220. To employ the second proximal retaining means 226, the second proximal sliding knob 324 (see Fig. 35) is moved distally until the proximal end of the second proximal releasing means 230 is withdrawn from the second proximal retaining means 226, as previously described. The proximal end 108 of the main body prosthesis 120 is thereby finally released from the catheter shaft 216, as Fig. 26 shows. To employ the distal retaining means 220, the distal sliding knob 326 (see Fig. 35) is moved distally until the proximal end of the distal releasing means 232 is withdrawn from the distal retaining means 220. The distal end 110 of the main body prosthesis 120 is thereby free to self-expand to its final deployment configuration, as Fig. 30 shows. Each of these steps will be described in greater detail in section V. It is to be appreciated that the sliding buttons or knobs may all be positioned on the first side 304 of the handle, or all may be positioned on the second side 306 of the handle, or may be positioned with one or more on the first side 304 and one or more on the second side 306, as shown. It should also be appreciated that the knobs 322, 324, 326, can comprise separate components that are not part of the handle assembly 212, i.e., on the outer jacket 210.

The proximal and distal retaining means 218, 220, desirably cooperate with a release system 328 positioned within the handle housing 290 (see Figs. 37 and 38). Each sliding knob 322, 324, 326, is coupled to a release slide 330, 332, 334, respectively, positioned within a track 336, 338, 340, respectively, in or on the release system 328 (see Figs. 41 through 43). Each release slide is coupled to the distal end of the releasing means, such as a release wire. It is to be appreciated that the release system 328 may also include an interlock system, such as

a mechanical linkage for controlling the order by which the slides may be moved. In addition, an interlock system could also include a mechanical linkage to the jacket retraction slide 310. This feature would prevent the activation of the release slides until the jacket had been retracted to a predetermined position. It is also to be appreciated that the sliding knobs may include a symbol to indicate to the clinician an appropriate order of deployment.

As described, the main body prosthesis 120 is not released immediately from proximal end to distal end as the jacket 210 is withdrawn. The proximal and distal stent or stents 130, 134, are released in a secondary operation, which follows the withdrawal of the outer jacket 210. Placement of the prosthesis extensions 140 can therefore comprise a next step in the deployment process.

1. Lumen Extension Deployment Catheter

After the main body of the prosthesis 120 has been partially or completely deployed, a lumen extension 140, or lumen extensions, are next to be implanted. An extension deployment catheter 350 is shown in Fig. 44. It is to be appreciated that the extension deployment catheter 350 may incorporate all the features disclosed in the description of the deployment catheter 200. The extension catheter is used for delivery and deployment of the lumen extensions 140 to the targeted site.

In the illustrated embodiment, the extension catheter 350 carries the lumen extension 140 in a radially reduced configuration to the targeted site. At the targeted site, the extension catheter 350 releases the radially reduced lumen extension 140, which expands radially, and is coupled to a lumen of the main body prosthesis 120, as will be described further in section V.

As shown in Figs. 44 through 45B, the extension catheter 350 comprises an inner assembly 358, an outer jacket 360, and a handle assembly 362. These components will now be individually described in greater detail.

a. The Inner Assembly

In the illustrated embodiment (see Fig. 45A), the inner assembly 358 comprises a central shaft 364, which functions as a carrier for the lumen extension 140, proximal retaining means 366, and an extension catheter tip component 368. The proximal retaining means 366 desirably retains at least a portion of the lumen extension 140 in a radially compressed or partially radially expanded condition prior to deployment and prior to coupling to the main body prosthesis 120. The proximal retaining means 366 also desirably includes a co-acting releasing means or mechanism 370 for maintaining the proximal retaining means 366 in a desired relationship with the lumen extension 140 prior to activation.

In an alternative embodiment (see Fig. 45B), the inner assembly may also include distal retaining means 367. The distal retaining means 367 desirably retains at least the distal portion of the lumen extension 140 in a radially compressed or partially radially expanded condition prior to deployment and prior to coupling to the main body prosthesis 120. The distal retaining means 367 also desirably includes a co-acting releasing means or mechanism 371 for maintaining the distal retaining means 367 in a desired relationship with the lumen extension 140 prior to activation.

b. The Central Shaft

In the embodiments shown in Fig. 45A and 45B, the central shaft 364 and the proximal and distal retaining means 366, 367 are located within the confines of the outer jacket 360. In this respect, the outer jacket 360 functions as an enclosure or jacket for the lumen

extension 140 on the shaft 364 (see Figs. 46A and B). In this arrangement, the catheter tip component 368 is attached to the proximal end of the central shaft 364, and the proximal end of the outer jacket 360 terminates adjacent the catheter tip component 368. Thus, the extension catheter tip component 368 extends outward beyond the outer jacket 360. The central shaft 364, the proximal releasing means 366, the distal releasing means 367 (shown in Fig. 45B), and the outer jacket 360 are coupled to the handle assembly 362 at the proximal end of the catheter handle assembly 362 (see Fig. 44). As can be seen in Fig. 46A and 46B, the lumen extension 140 is contained in a cavity 372 defined between the central shaft 364 and the outer jacket 360 in the proximal section of the extension catheter 350.

The central shaft 364 extends from the handle assembly 362 to the catheter tip component 368. The central shaft 364 may be made, e.g., from stainless steel or other suitable medical materials including other metals or polymers. The central shaft 364 comprises at least one lumen, and may comprise more than one lumen.

One lumen may be described as the central lumen 374 (see Fig. 47A and 47B), with an inner diameter between .010 and .120 inches, desirably between .020 and .060 inches and most desirably between .030 and .050 inches. As described, the central lumen 374 allows for the insertion of a guide wire, i.e., the first guide wire 30 or the second guide wire 40, up to 0.038″ diameter, for example. The catheter tip component 368, having the same features as described for the catheter tip 222 of the deployment catheter 200, also desirably has at least one lumen 376 (see Fig. 45A) configured to align with at least one lumen within the central shaft 364. This lumen 376 allows for the insertion of the guide wire through the central shaft 364 and through the extension catheter

tip component 368. Typically this lumen 376 will have an inner diameter between .010 and .120 inches, desirably between .020 and .060 inches and most desirably between .030 and .050 inches.

c. Proximal Retaining Means

The proximal retaining means 366 and the proximal releasing means 370 may function in the same or similar fashion as the retaining means 224, 226, and the releasing means 228, 230 embodied in the deployment catheter 200, as previously shown and described. As can be seen in Figs. 46A and 48A, in the illustrated embodiment, the proximal retaining means 366 comprises at least one suture, or sutures, 378 and/or equivalent structures, which are coupled to the lumen extension prosthetic material 112, or to one or more stents 150 on the lumen extension 140. The suture 378 is, in turn, looped around the proximal releasing means 370, e.g., a release wire 380, when the release wire 380 is in its proximal-most position, as Figs. 46A and 48A show. Distal retraction of the wire 380 positioned within a releasing wire lumen 381 (see Figs. 45A and 47A) withdraws the wire 380 from the suture loop 378, and allows the proximal end 142 of the lumen extension 140 to radially expand, as can be seen in Figs. 70 and 71. In an alternative embodiment, the suture 378 may comprise more than one suture, i.e., two or more suture loops. Fig. 48C shows the path of two suture loops 378 looped around the release wire 380.

As described for the main body prosthesis 120, belt loops or the like may be provided on the lumen extensions 140 as well to guide and support the suture loop(s) along the path of the suture loop. The belt loops can be spaced at desired circumferential intervals, such as every ninety degrees, for example.

As can be seen in Fig. 45A, the proximal releasing means 370 comprises a proximal release hub 397 positioned

over the central shaft 364, and the release wire 380. The proximal release hub 397 may include a small hole or lumen 398 in the proximal end of the hub 397 that is in fluid communication with the proximal releasing wire lumen 381 within the central shaft 364. Each lumen 381, 398 desirably include a diameter sufficiently large to accommodate the release wire 380 extending from the handle assembly 362 to beyond the release hub 397. It is to be appreciated that the release wire 380 may extend external the shaft 364 as well.

d. Distal Retaining Means

In an alternative embodiment, the distal retaining means 367 and the distal releasing means 371 may function in the same or similar fashion as the retaining means 220, and the releasing means 232 embodied in the deployment catheter 200, as previously shown and described. As can be seen in Figs. 46B and 48B, the distal retaining means 367 comprises at least one suture, or sutures, 379 and/or equivalent structures, which are coupled to the lumen extension prosthetic material 112, or to one or more stents 150 on the lumen extension 140. The suture 379 is, in turn, looped around the distal releasing means 371, e.g., a release wire 383, when the release wire 383 is in its proximal-most position, as Figs. 46B and 48B show. Distal retraction of the wire 383 positioned within a releasing wire lumen 385 (see Figs. 45B 47B) withdraws the wire 383 from the suture loop 379, and allows the distal end 144 of the lumen extension 140 to radially expand. As described for the proximal retaining means 366, the suture 379 may also comprise more than one suture, i.e., two or more suture loops. Fig. 48C shows the path of two suture loops 378 looped around the release wire 380. This path may also be used for suture loops 379 looped around the release wire 383.

As can be seen in Fig. 45B, the distal releasing

means 371 comprises a distal release hub 399 positioned over the central shaft 364, and the release wire 383. The distal release hub 399 may include a small hole or lumen 395 in the proximal end of the hub 399 that is in fluid communication with the distal releasing wire lumen 385 within the central shaft 364. Each lumen 385, 395 desirably include a diameter sufficiently large to accommodate the release wire 383 extending from the handle assembly 362 to beyond the release hub 399. It is to be appreciated that the release wire 383 may extend external the shaft 364 as well.

B. The Outer Jacket

The outer jacket 360 may function in the same or similar fashion as described for the outer jacket 210 embodied in the deployment catheter 200. The outer jacket 360 also serves to restrain the stents 146 and 150 on the lumen extension 140 from expanding and allows for a controlled deployment of the lumen extension 140 within a lumen of the main body prosthesis 120. In the illustrated arrangement, the outer jacket 360 is coupled to an actuator or knob 382 on the handle assembly 362, as will be described in greater detail below.

As Figs. 46A and 46B show, the outer jacket 360 extends proximally over a spacer 384 and lumen extension 140 and terminates adjacent the distal end of the catheter tip component 368. Typically, the outer jacket 360 can be made of a polymer tube or similar materials known in the art. In one embodiment, the jacket 360 may be free of structural reinforcement. In an alternative embodiment (shown in Fig. 46C), the jacket 360 may include structural reinforcement, such as but not limited to, a wire or rod 361 positioned longitudinally along a length of the jacket, and/or a wire or rod 363 positioned helically around a length of the jacket. The structural reinforcement may also be in the form of a coil(s) or

braided wire, for example. The plasticity of the structural reinforcement may be altered to affect the flexibility of the jacket 360 depending on a selected application. In addition, the structural reinforcement may extend along the full length of the jacket 360, or may be positioned along only a portion or portions of the length of the jacket. The structural reinforcement may be embedded within the jacket 360, or may be coupled to the interior or exterior surface of the jacket.

If desired, and as shown in Fig. 44B, a stationary outer jacket 365 may be provided that extends from the proximal end of the handle assembly 362. The jacket 360 slides within the stationary jacket 365. The stationary jacket 365 provides a seal interface with a hemostatic valve at the access site. The stationary jacket 365 can be made of a suitable medical grade plastic, such as Fluroinated Ethylene Propylene (FEP) as non-limiting example. The stationary outer jacket 365 provides column strength and lubricity to reduce friction during sliding actuation of the jacket 360. The stationary outer jacket 365 may also be provided for the prosthesis deployment catheter 200 for the same purposes.

C. Handle Assembly

The handle assembly 362 may function in the same or similar fashion as described for the handle assembly 212 embodied in the deployment catheter 200. The handle assembly 362 provides the operator with longitudinal or axial control and rotational control of the extension deployment catheter 350 within the body and provides access to the actuator(s) or control means for deploying the lumen extension 140.

Referring to Figs. 49 and 50, the handle assembly 362 comprises a handle body 386, a jacket retraction means 382, which is connected to the distal end of the outer jacket 360, and at least one knob or button 392

which is attached to the distal end of the proximal releasing means 370. It is to be appreciated that the handle assembly 362 may also include at least one knob or button 393 (see Fig. 49B) attached to an optional distal releasing means 371 and the knob or button may function in the same or similar fashion as described below for the proximal releasing means 370.

In the illustrated embodiment, the central shaft 364 is captured within the handle 362 and has a guide wire receiving luer 388 and an infusion valve 390 coupled to its distal end, which is located at the distal end of the handle assembly 362 (see Figs. 50 and 51). This feature prevents the position of the lumen extension 140 from moving relative to the handle body 362 while the outer jacket 360 is retracted, and allows for irrigation or flushing of the catheter shaft 364, such as with a saline solution.

To withdraw the outer jacket 360 from the catheter tip 368 and expose the lumen extension 140, jacket retraction means, such as the jacket retraction knob 382 may be used. The jacket retraction means 382 may include a variety of different mechanisms to selectively control the retraction of the jacket 360 from the catheter tip 368. In the illustrated embodiment, the jacket retraction means comprises two co-acting retraction knobs 382 which are available for the clinician, one positioned on each side of the handle 362.

The jacket retraction knob 382 is used to retract the jacket 360 from the lumen extension 140. The jacket retraction knob 382 is moved distally until the outer jacket 360 is free of the lumen extension 140 (see Fig. 70). The portion or portions of the lumen extension 140 that are not coupled to the proximal retaining means 366 are free to self-expand, as Fig. 70 shows. However, the portions of the lumen extension 140 that are coupled to

the proximal retaining means 366 are still restrained from self-expansion, despite withdrawal of the outer jacket 360. The stent structure of the lumen extension 140 is thereby kept restrained in a close relationship against the central shaft 364 while the outer jacket 360 is retracted. The proximal retaining means 366 prevents the lumen extension 140 from moving relative to the central shaft 364 during retraction of the outer jacket 360, which potentially minimizes blood flow through the lumen extension 140 during the deployment process. Furthermore, as described, the lumen extension 140 is not "pushed out" of the extension catheter 350. The lumen extension 140 therefore need not have longitudinal stiffness or a stent structure with a "spine".

To employ the proximal retaining means 366, the proximal release sliding knob 392 (see Figs. 49A and 50) is moved distally until the proximal end of the proximal releasing means 370 is withdrawn from the proximal retaining means 366, as previously described. In the illustrated embodiment, the proximal release wire 380 is positioned within the loops of the suture loop 378, as seen in Figs. 46A and 48A. As the proximal release wire 380 is withdrawn from the suture loop 378, the suture loop 378 releases its retentive feature, yet may remain coupled to the prosthesis material 112. The proximal end 142 of the lumen extension 140 is thereby free to self-expand to its deployment configuration and couple itself within the lumen of the main body prosthesis 120, as Figs. 70 and 71 show. The natural flow of fluid through the new extension 140 provides sufficient force to cause the restraint mechanism of the lumen extension 140 to engage the co-acting restraint mechanism of the main body prosthesis 120. The lumen extension stent and/or the outwardly extending apices 147 of the lumen extension stent 150 engage the mating outwardly extending apices

136 of the main body prosthesis stent 134 (see Fig. 10B). Each of these steps will be described in greater detail in section V. It is to be appreciated that the sliding buttons or knobs may all be positioned on one side of the handle, or all may be positioned on the opposite side of the handle, or may be positioned on both sides, as shown. It should also be appreciated that the knobs 382 and 392 can comprise separate components that are not part of the handle assembly 362, i.e., on the outer jacket 360.

The proximal retaining means 366 desirably cooperate with a release system 394 positioned within the handle housing 386. Proximal release sliding knob 392 is coupled to a release slide 396 positioned within a track 398 in or on the release system 394 (see Fig. 51). The release slide 396 is coupled to the distal end of the releasing means 370, such as the release wire 380. It is to be appreciated that the release system 394 may also include an interlock system, such as a mechanical linkage for controlling the order by which the slides may be moved. In addition, an interlock system could also include a mechanical linkage to the jacket retraction slide 382. This feature would prevent the activation of the release slides until the jacket had been retracted to a predetermined position. It is also to be appreciated that the sliding knobs may include a symbol to indicate to the clinician an appropriate order of deployment.

As described, the lumen extension 140 is not released immediately from proximal end to distal end as the jacket 360 is withdrawn. The lumen extension stent or stents 146 and 150 may be released in a secondary operation, which follows the withdrawal of the outer jacket 360. Placement of the prosthesis extensions 140 can therefore comprise a final step in the deployment process.

D. Fastener Device And Fastener

As previously described, one or more fasteners 402 (see Fig. 52) may be introduced by a fastener device 400 to anchor the prosthesis 100 in place. Typically the fasteners 402 will be introduced at the proximal end of the main body prosthesis 120; however, it should be appreciated that the fasteners can be introduced in any part of the prosthesis 100, including the lumen extensions 140, to anchor it in place. In addition, the fasteners 402 may also serve to provide apposition of the prosthesis material 112 to the hollow body organ or vessel wall. Fasteners may also be used to seal and/or repair leaks or seepage of fluid (e.g., around the proximal stents and/or distal stents of the prosthesis 100). One or more fasteners 402 may be introduced into the prosthesis 100 at different times or at the same time during the procedure.

As can be seen in Figs. 53 and 54, the fastener tool 400 desirably comprises a handle assembly 404 including a control assembly 406 and an indication assembly 408. A fastener delivery shaft 409, having a fastener driver 411 at its proximal end 410, is coupled to the proximal end of the handle assembly 404 for delivery of the fastener 402. Coupled to the distal end of the handle assembly may be an irrigation port or infusion valve 422.

The handle assembly 404 provides the fastening control feature for the clinician. Positioned within the handle assembly 404 is the control assembly 406. The control assembly provides motion control, such as a forward and reverse drive feature, for turning or otherwise moving the fastener 402 to or from a fastening position. The control assembly desirably includes a forward control button 412 and a reverse control button 414. The forward and reverse control buttons 412, 414 provide the clinician an ergonomic and single finger control of the fastener device 400.

The handle assembly desirably includes an indication assembly 408 to provide control information to the clinician. The indication assembly may include indication lights, i.e., LEDs, and/or the ability to produce audible signals (tones) to provide visual and/or audible indication of forward or reverse movement of the fastener 402, for example, by way of a variety of tones and/or a forward light 416 and a reverse light 418. Additionally, the indication assembly may include status tones and/or a status light 420 to provide a variety of information back to the clinician. The tones may use a variety of pitches or pulses, for example, and the status light 420 may use a variety a flash signals and illumination times, for example, to provide these different indications for the clinician, such as error indication, position indication, and timing indication, for example.

Further details of the fastener device 400 and fastener 402 can be found in United States Patent Application Serial No. 10/307,226, filed November 29, 2002, and entitled "Intraluminal Prosthesis Attachment Systems and Methods," and in U.S. Patent Application Serial No. 10/786,465, filed February 29, 2004 and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ," which are both incorporated herein by reference.

In this embodiment, the proximal coil 422 of the fastener 402 is formed to produce a diagonal member 424, which crosses the diameter of the helical fastener. The distal end of the fastener 402 comprises a sharpened tip 426, such as a conical tip or a chiseled tip, for example, to aid in the ease of tissue penetration. Similar helical fasteners are described in U.S. Patent No. 5,964,772; 5,824,008; 5,582,616; and 6,296,656, the full disclosures of which are incorporated herein by reference.

In an alternative embodiment, the fastener device 400 and a fastener 430 may comprise features allowing the fastener 430 to be releasably secured to the fastener driver 432. As can be seen in Figs. 79A and 79B, the proximal coil 434 of the helical fastener 430 desirably includes a diagonal member 436, which crosses the diameter of the fastener 430. The diagonal member 436 may bisect the diameter of the fastener 430, or may be offset, forming a "D" shaped proximal coil 434, as shown. The diagonal member 436 desirably comes completely across the diameter to prevent the fastener 430 from being an open coil and to control the depth of penetration into the tissue. In addition, the diagonal member 436 can be attached to a previous coil, as shown, to strengthen the entire structure and provide a retentive shape for a fastener driver 432. This attachment could be achieved via welding, adhesive or any other suitable means.

Located at the proximal end of the fastener delivery shaft 410 is the fastener driver 432. In the illustrated embodiment (see Figs. 80 and 81), the fastener driver 432 includes a fastener carrier 438 positioned within a threaded fastener housing 439. The threaded fastener housing 439 may include tabs 437 or other coupling means so as to snap fit or couple to the fastener carrier 438 for convenient replacement. The coupling between the driver 432 and carrier 438 can take different forms – e.g., magnets, graspers, or other suitable mechanical connection. In the embodiment illustrated in Figs. 80 and 81, the driver 432 and carrier 438 are integrally connected as a single unit.

The carrier 438 is sized and configured to engage a selected fastener 430. The diagonal member 436 serves to define a shape, such as a "D" shape, to engage the carrier 438, which rotates the fastener 430 positioned over the carrier 438 to achieve fastening the prosthesis

to tissue. The diagonal member 436 also serves as a stop to prevent the helical fastener 430 from penetrating too far into the tissue.

As can be seen in Figs. 80 and 81, a fastener 430 is positioned within the fastener housing 439 and over the carrier 438. The carrier 438 includes a release latch 440. The release latch 440 may be spring loaded, magnetic, or lever action, for example. The latch 440 prevents the premature release of the fastener 430. The release latch 440 desirably requires a force to overcome the securing force of the latch. For example, the release latch 440 may be overcome by a pulling force, e.g., the fastener 430 is being fastened through the prosthesis and within tissue and the pulling force of the fastener turning or screwing into tissue may overcome the securing force of the release latch. Alternatively, the release latch 440 may be overcome by a magnetic force activated by the clinician by pressing a release button 444 on the handle assembly 404 (shown in Fig. 86). In one embodiment shown in Figs. 82A and 82B, the release latch 440 includes a lever arm 442 to provide the latching force. As the carrier 438 is rotated to deploy the fastener 430, the force of the fastener 430 rotating into the tissue may be adequate to overcome the force of the release latch 440. As seen in Fig. 82A, the fastener 430 remains fastened to the carrier 438 by way of the fastener release latch 440. As seen in Fig. 82B, further rotation of the fastener 430 into tissue will cause each coil of the fastener to overcome the force of the release latch 440 and allow the fastener 430 to exit off of the carrier 438.

In an alternative embodiment, the release latch 440 may include a release spring 445, as seen in Fig. 82C. The release spring 445 is sized and configured to provide a sufficient force to maintain the fastener 430 on the

carrier 438, and yet allow the fastener 430 to overcome the force of the release spring 445 and release latch 440 as the fastener is being screwed into tissue.

The fastener housing 439 desirably includes a predetermined amount of internal threads 441 (e.g., two or three threads). In this configuration, the threaded portion of the housing 439 may not be continuous throughout the length of the housing. The threads 441 engage the fastener 430 when the fastener is being loaded onto the fastener driver 432 (as described below) and also partially drive the helical fastener 430 out of the fastener driver 432 and into tissue. Desirably, the threaded portion of the threaded housing terminates a predetermined distance from the housing tip 443. This unthreaded portion of the threaded housing 439 provides an area in which the fastener 430 can be rotated but not be driven out of the fastener driver 432. This unthreaded feature of the housing 439 allows the fastener 430 to pull itself out of the fastener driver 432 when rotated by the driver only as long as the fastener 430 has been previously engaged with the prosthesis 120 and tissue. This feature ensures a more uniform depth of penetration for the fastener 430.

A helical fastener, such as 402 and 430, for example, may be positioned in a fastener cassette 446, as seen in Figs. 83 and 84. The fastener cassette 446 may take on any convenient shape, such as a rectangle or circle, as shown, and may include any convenient number of fastener receptacles 448, such as six, although any number may be used. The cassette 446 may be used to store and retain fasteners during shipment, and also to provide a convenient means to present the fastener 430, for example, to the fastener device 400 during a medical procedure.

As seen in Figs. 83 and 84, the fastener receptacle

448 is sized and configured to allow the proximal end 410 and the fastener driver 432 of the fastener device 400 access to the seated fastener 430. The fastener 430 may be positioned on a receptacle post 449, to hold the fastener 430 within the receptacle 448. Or alternately, the fastener 430 may be held within the receptacle 448 through interference between the fastener 430 and the receptacle 448, or by penetrating the fastener tip 426 into a material at the base of the receptacle 448. The receptacle post 449 may include a receptacle post spring 447, allowing the receptacle post 449 to retreat into the receptacle 448 as the fastener driver 432 is inserted into the receptacle 448 to position the fastener 430 on to the carrier 438.

Figs. 85 and 86 show an embodiment of a fastener 430 being positioned within the fastener driver 432. As can be seen the fastener driver 432 is positioned on top of the receptacle 448 and gently inserted into the receptacle. The force of the insertion allows the fastener 430 to overcome the force of the release latch 440 on the carrier 438 and to be positioned over the carrier 438. The fastener driver is then reversed, using the control assembly 406 provided on the fastener driver handle 404. The internal threads 441 of the threaded housing 439 draw the fastener 430 into the fastener driver 432 and into position for deployment. Fig. 86 shows the fastener 430 removed from the cassette 446 and positioned on the fastener driver 432. It is to be appreciated that the cassette 446 can be used to hold a variety of fastener shapes and sizes, and is not limited to the fastener 430, as described.

E. Steerable Guide Device

A steerable guide device 450 may be used to establish an open path through which an operative tool, such as the fastener device 400, can be deployed for use.

Figs. 55 and 56 show an embodiment of the steerable guide device 450. The steerable guide device comprises a flexible guide tube 452 carried by a handle 454. The handle is sized and configured to be ergonomically held by the clinician to introduce the guide tube 452 to the targeted site.

In order to establish an open path for the fastener device 400, the steerable guide device 450 includes an interior guide passage 456 which extends through the interior portion of the handle 454 continuously and into and through the guide tube 452. The distal end of the handle 454 may also include a seal 457 to restrict the flow of fluids through the guide tube 452. During introduction of the guide tube through the vasculature to the targeted site, an obturator or dilator 458 having a tip component 459 (see Fig. 57) is positioned within the guide tube 452 in order to seal the guide tube and restrict the flow of fluids through the guide tube 452, to provide an atraumatic tip for guiding through the vasculature, and to provide a guide wire lumen 470.

The handle assembly desirably includes a rotatable steering assembly 460 and a flushing port 462. The steering assembly 460 is used to deflect the proximal end 464 of the guide tube 452 to a bent or deflected configuration, as will be described later. The steering assembly 460 is rotated in a desired direction, causing the proximal end 464 to bend or deflect in a predetermined configuration. A radiopaque marker 466 can be placed on the proximal end region 464 of the guide tube 452 to allow for fluoroscopic visualization of the orientation of the deflected end region. In the bent or deflected configuration, the proximal end 464 can be oriented in a desired relationship with the targeted site.

Further details of the steerable guide device 450

can be found in United States Patent Application Serial No. No. --/------, (to be supplied), filed 20 October 2005, and entitled "Devices, Systems, and Methods for Guiding an Operative Tool Into an Interior Body Region," which is incorporated herein by reference.

V. DETAILED IMPLANTATION METHODS

The generally described steps of implantation of the prosthesis 100 provided in Section II will now be described in greater detail. In the illustrated embodiment, deployment of the bifurcated prosthesis 100 may generally be achieved in a twelve step process, for example, and is shown generally in Figs. 58 through 78. The exemplary embodiment will describe the systems, methods, and uses of the tools for implanting the prosthesis 100. It is to be understood that these same or similar systems, methods, and tools may be used to implant other prosthesis configurations in other areas of the body as well. Throughout the implantation process, image guidance may be used and in conjunction with radiopaque markers positioned on the prosthesis 100 and deployment tools.

Access to the vascular system is commonly provided through the use of introducers known in the art. A hemostasis introducer sheath (not shown), for example, may be first positioned in the left femoral artery, providing access for the implantation tools. A second introducer sheath (not shown) may also be positioned in the right femoral artery, providing access for the implantation tools. It is to be understood that alternative access points may also be used. Access at both the left femoral artery and the right femoral artery, for example, allows for multiple implantation tools to be positioned within the vasculature at the same time, allowing the implantation procedure to be efficiently performed.

A. Position Main Body Prosthesis

A first step includes positioning the main body prosthesis 120 at the desired location. From either the left or right femoral artery, under image guidance, the first guide wire 30 is advanced into the ipsilateral iliac artery and to the descending aorta. The deployment catheter 200 is then navigated over the first guide wire 30 to the desired location within the body, (e.g., aortic aneurysm), for deployment of the main body prosthesis 120 (as Fig. 58 shows). A conventional hemostatic valve arrangement may be used at the access site (shown for purposes of illustration in Fig. 44B).

B. Retract Outer Jacket

Next, the outer jacket 210 is retracted in a distal or caudal direction to expose the main body prosthesis 120. By first rotating the starting knob 302 on the handle assembly 212, the outer jacket 210 is initially retracted from its secure position on the catheter tip 222. After the mechanical advantage provided by the rotation of the starting knob 302 has retracted the outer jacket 210 away from the catheter tip 222, the jacket sliding knob 294 on the handle 212 may be used to further retract the jacket 210 and fully expose the main body prosthesis 120 (as Figs. 59 and 60 show). The unrestrained portion or portions of the main body prosthesis 120 self-expand, as can be seen in Fig. 60. Optionally, the first lumen 126 may not be radially restrained, but still restrained in relation to the central shaft 216 (see Fig. 32), so as the outer jacket 210 is retracted, the first lumen 126 may self expand as well, as can be seen in Fig. 61. As Figs. 59 through 61 show, both during and after retraction of the outer jacket 210, the main body prosthesis 120 maintains its position relative to the central shaft 216 due to the proximal and distal retaining means 218, 220, coupled to

the main body prosthesis 120.

It should be appreciated that the withdrawal of the outer jacket 210 and the withdrawal of the proximal and distal releasing means 228, 230, 232, or any combination thereof, can be accomplished in a single step or process or in multiple steps. In this arrangement, a single activation mechanism can be jointly coupled to the outer jacket 210 and any or all of the releasing means 228, 230, 232, so that the outer jacket 210 and releasing means 228, 230, 232, are withdrawn in a single step, or multiple steps.

C. Release First Proximal Retaining Means

In the third general step of the deployment process, following the withdrawal of the outer jacket 210, the first proximal sliding knob 322 on the handle assembly 212 is moved distally, which causes the proximal end of the first proximal releasing means 228, i.e., the first proximal release wire 250, to be withdrawn from the first proximal retaining means 224, i.e., the suture loop 252, and allows the restrained stent or stents 130, and the proximal end 108 of the main body prosthesis 120 as a whole, to self-expand radially to the first stage deployment configuration, as seen in Fig. 62. The proximal end 108 of the main body prosthesis 120 desirably radially expands either partially or fully toward the internal walls of the vessel or hollow body organ.

At this point in the deployment process, both the proximal and distal ends of the main body prosthesis 120 are being held and controlled, respectively, by the second proximal retaining means 226 and the distal retaining means 232. This allows the practitioner to adjust the position of the main body prosthesis 120 either longitudinally or rotationally before the next stage (fasten proximal end), as well as hold and maintain

control of the main body prosthesis 120 during the next stage (fasten proximal means). Further, because the main body prosthesis 120 can be selectively retained and controlled from both proximal and distal ends during deployment and anchoring, the prosthesis 120 itself need not be self-supporting, but can instead be compliant in either or both longitudinal and/or rotational dimensions, and thereby be capable of conforming and accommodating anatomic changes that may occur after implantation (e.g., shrinkage of the aneurysm).

D. Fasten Proximal End

The fourth general stage comprises fastening the proximal end 108 of the main body prosthesis 120 to the internal walls of the vessel or hollow body organ. From the right femoral artery, under image guidance, a second guide wire 40 is advanced using a conventional intravascular approach into the contralateral iliac artery and to the descending aorta. However, other access sites and methods can be utilized. The guide wire 40 desirably extends through the second expanded lumen 128 and through the proximal opening 122 of the main body prosthesis 120 (see Fig. 63). Next, the steerable guide device 450, with the obturator 458 positioned within the interior guide passage 456, is then navigated over the second guide wire 40 to the desired location with respect to the main body prosthesis 120 (see Fig. 64). Once the steerable guide device 450 is in position, the obturator 458 and the second guide wire 40 are both removed from the interior guide passage 456 and from the body.

By rotating the steering assembly 460 (see Fig. 55), and still employing fluoroscopy visualization, the clinician deflects the proximal end region 464 - and rotates the handle 454 to rotate the flexible guide tube 452 if necessary - to orient the proximal opening 468 of the passage 456 in a desired facing relationship with the

site where introduction of a fastener 402 is desired. An operative tool, such as the fastener device 400 is then inserted through the interior guide passage 456 of the steerable guide device 450, and advanced until a fastener, such as the fastener 402, is located for deployment in relation to the now-oriented proximal opening 468, as Fig. 65 shows. As the fastener device 400 is advanced out of the steerable guide device 450 and contacts the wall of the main body prosthesis 120, a resultant force is applied to the proximal end 464 of the steerable guide 450 which moves in the opposite direction of the fastener device proximal end 410. The resultant force causes the proximal end 464 of the steerable guide 450 to deflect until it contacts the opposite wall of the main body prosthesis within the lumen or hollow body organ. In this way, the force applied to the main body prosthesis 120 and vascular wall from the proximal end 410 of the fastener device 400 is partially resolved through the steerable guide 450 within the vessel or hollow body organ. A representative embodiment of an endovascular device that, in use, applies a helical fastener is described in U.S. Patent Application No. 10/786,465, filed February 25, 2004, and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ," which is incorporated herein by reference.

The fastener device 400 can then be actuated to apply a fastener 402 to the proximal end 108 of the main body prosthesis 120 and into the surrounding tissue (see Fig. 66). If the fastener device 400 is a single fire device, i.e., it carries only one fastener 402, the fastener device 400 is withdrawn through the interior guide passage 456 and a new fastener 402 is mounted. See Figs 85 and 86 for one embodiment of the fastener 430 being mounted to the fastener device 400. The proximal

end region 464 of the steerable device 450 is reoriented in facing relationship with a new fastening site. The fastener device 400 is inserted back through the interior guide passage 456 to apply a second fastener 402 to the new fastening site (see Fig. 67). This sequence is repeated until a desired number and array of fasteners 402 are applied to the main body prosthesis 120, as can be seen in Fig. 68.

At this point, the fastener device 400 is withdrawn, leaving the steerable guide device 450 in place. The obturator 458 is repositioned within the interior guide passage 456, and the second guide wire 40 is navigated through the obturator lumen 470 to the desired location with respect to the main body prosthesis 120. Once the second guide wire 40 is in position, the steerable guide device 450 and the obturator 458 are both removed from the interior guide passage 456 and from the body leaving the second guide wire 40 in position within the vasculature.

Throughout this stage of the deployment process, both the proximal and distal ends of the main body prosthesis 120 can being held and controlled, respectively, by the second proximal retaining means 226 and the distal retaining means 232, while fastening occurs.

E. Position First Lumen Extension

In the fifth general stage of the deployment process, following the fastening of the proximal end 108 of the main body prosthesis 120, the extension deployment catheter 350 is used to position a lumen extension 140 for deployment within a lumen of the main body prosthesis 120. From the left or right femoral artery, under image guidance, the extension catheter 350 is navigated over the second guide wire 40 to the desired location, i.e., telescopically positioned partially within the second

lumen 128 of the main body prosthesis 120, as Fig. 69 shows. A conventional hemostatic valve arrangement may be used at the access site (shown for purposes of illustration in Fig. 44B).

F. Retract Extension Catheter Outer Jacket

Next, the extension catheter's outer jacket 360 must be retracted in a distal or caudal direction to expose the lumen extension 140. The jacket sliding knob 382 on the extension catheter handle 362 is urged in a distal direction to retract the jacket 360 and fully expose the lumen extension 140. The unrestrained portion or portions of the lumen extension 140 self-expand (see Fig. 70). Both during and after retraction of the outer jacket 360, the lumen extension 140 maintains its position relative to the central shaft 356 due to the proximal retaining means 366, coupled to the lumen extension 140.

G. Release Lumen Extension Proximal Retaining Means

In the seventh general step of the deployment process, following the withdrawal of the extension catheter outer jacket 360, the proximal sliding knob 382 on the extension catheter handle assembly 362 is moved distally, which causes the proximal end of the proximal releasing means 370, i.e., the proximal release wire 380, to be withdrawn from the proximal retaining means 366, i.e., the suture loop 378, and allows the restrained stent or stents 150, and the proximal end 142 of the lumen extension 140, to self-expand radially to the deployment configuration, as seen in Figs. 70 and 71. The proximal end 142 of the lumen extension 140 desirably enlarges to contact the internal walls of the second lumen 128 of the main body prosthesis 140. The natural flow of fluid through the lumen extension 140 provides sufficient force to cause the restraint mechanism of the lumen extension 140 to engage the co-acting restraint

mechanism of the main body prosthesis 120. The lumen extension stent and/or outwardly extending apices 147 of the lumen extension stent 150 engage the mating outwardly extending apices 136 of the distal stent 134 positioned within the second lumen 128 of the main body prosthesis 120 (as best seen in Fig. 10B) in order to couple the lumen extension 140 to the main body prosthesis 120.

Prior to withdrawing the extension catheter 350, the outer jacket 360 is desirably repositioned in an abutting relationship with the catheter tip 368. The jacket sliding knob 382 on the extension catheter handle 362 is urged in a proximal direction to reposition the jacket 360 in a pre-deployment configuration. The extension catheter 350 may now be withdrawn and removed from the body. The second guide wire 40 may either be removed, or may remain until the deployment process is completed.

H. Release Second Proximal Retaining Means

In the eighth general stage of the deployment process, following the deployment of a first lumen extension 140, the second proximal retaining means 226 is released. To release the proximal end 108 of the main body prosthesis 120, the second proximal release sliding knob 324 on the handle 212 is moved distally, which causes the proximal end of the second proximal releasing means 230, i.e., the second proximal release wire 268, to be withdrawn from the prosthesis material 112 and the stabilizing arm apertures 264, and allows the stabilizing arms 256 to release from the proximal end 108 of the main body prosthesis 120, and spring proximally, as shown in Fig. 72. The proximal end 108 of the main body prosthesis 120 is no longer in a restrained relationship with the central shaft 216.

I. Release Distal Retaining Means

In the ninth general stage of the deployment process, following the release of the second proximal

retaining means 226, the distal retaining means 220 is released. To release the distal end 110 of the main body prosthesis 140, the distal release sliding knob 326 on the handle 212 is moved distally, which causes the proximal end of the distal releasing means 232, i.e., the distal release wire 282, to be withdrawn from the distal retaining means 220, i.e., the distal suture loop 274, and allows the restrained stent or stents 134 to self-expand radially to the second stage deployment configuration, as seen in Fig. 73. As previously mentioned, alternatively, the stent or stents 140 are not necessarily radially restrained by the distal retaining means 226. The main body prosthesis 120 is no longer in a restrained relationship with the central shaft 216.

Prior to withdrawing the deployment catheter 200, the outer jacket 210 is desirably repositioned in an abutting relationship with the catheter tip 222. The jacket sliding knob 294 on the catheter handle 212 is urged in a proximal direction to reposition the jacket 210 in a pre-deployment configuration. The deployment catheter 200 may now be withdrawn from the body, leaving the first guide wire 30 within the vasculature (see Fig. 74).

J. Position Second Lumen Extension

In the tenth general stage of the deployment process, following the release of the distal retaining means 220 and withdrawal of the deployment catheter 200, the second lumen extension 140 is positioned for deployment. The general steps as describe for the deployment of the first lumen extension 140 are the same or similar, but will be repeated here for clarity. The extension deployment catheter 350 is again used to position the second lumen extension 140 for deployment within a lumen of the main body prosthesis 120. From the left or right femoral artery, for example, under image

guidance, the extension catheter 350 is navigated over the first guide wire 30 to the desired location, i.e., telescopically positioned partially within the first lumen 126 of the main body prosthesis 120, as Fig. 75 shows. Again, as previously described, a conventional hemostatic valve arrangement may be used at the access site (shown for purposes of illustration in Fig. 44B).

K. Retract Extension Catheter Outer Jacket

Next, the extension catheter's outer jacket 360 must be retracted in a distal or caudal direction to expose the lumen extension 140. The jacket sliding knob 382 on the extension catheter handle 362 is urged in a distal direction to retract the jacket 360 and fully expose the lumen extension 140. The unrestrained portion or portions of the lumen extension 140 self-expand (see Figs. 75 and 76). As Fig. 76 shows, both during and after retraction of the outer jacket 360, the lumen extension 140 maintains its position relative to the central shaft 356 due to the proximal retaining means 366, coupled to the lumen extension 140.

L. Release Lumen Extension Proximal Retaining Means

In the twelfth general step of the deployment process, following the withdrawal of the extension catheter outer jacket 360, the proximal sliding knob 382 on the extension catheter handle assembly 362 is moved distally, which causes the proximal end of the proximal releasing means 370, i.e., the proximal release wire 380, to be withdrawn from the proximal retaining means 366, i.e., the suture loop 378, and allows the restrained stent or stents 150, and the proximal end 142 of the lumen extension 140, to self-expand radially to the deployment configuration, as seen in Fig. 77. The proximal end 142 of the lumen extension 140 desirably enlarges to contact the internal walls of the first lumen

126 of the main body prosthesis 140. The natural flow of fluid through the lumen extension 140 provides sufficient force to cause the restraint mechanism of the lumen extension 140 to engage the co-acting restraint mechanism of the main body prosthesis 120. The lumen extension stent and/or the outwardly extending apices 147 of the lumen extension stent 150 engage the mating outwardly extending apices 136 of the distal stent 134 positioned within the first lumen 126 of the main body prosthesis 120 (as best seen in Fig. 10B) in order to couple the lumen extension 140 to the main body prosthesis 120.

Prior to withdrawing the extension catheter 350, the outer jacket 360 is desirably repositioned in an abutting relationship with the catheter tip 368. The jacket sliding knob 382 on the extension catheter handle 362 is urged in a proximal direction to reposition the jacket 360 in a pre-deployment configuration. The extension catheter 350 may now be withdrawn and removed from the body. Both the first guide wire 30 and the second guide wire 40 may now be removed to complete the deployment process of the bifurcated prosthesis 100, as can be seen in Fig. 78.

It is to be appreciated that the general steps just described do not necessarily need to follow the order in which they were described. For example, the second proximal retaining means may be released prior to the deployment of the first lumen extension 140, and the second guide wire may be removed prior to the completion of the deployment process. It is also to be appreciated that fasteners may be applied to the lumen extensions as well to connect the lumen extensions to the iliac arteries.

It will also be appreciated that the components and/or features of the preferred embodiments described herein may be used together or separately, while the

depicted methods and devices may be combined or modified in whole or in part. It is contemplated that the components of the guiding device, fastener device, and helical fastener may be alternately oriented relative to each other, for example, offset, bi-axial, etc. Further, it will be understood that the various embodiments may be used in additional procedures not described herein, such as vascular trauma, arterial dissections, artificial heart valve attachment and attachment of other prosthetic device within the vascular system and generally within the body.

The foregoing is considered as illustrative only of the principles of the invention. Furthermore, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

The desired embodiments of the invention are described above in detail for the purpose of setting forth a complete disclosure and for the sake of explanation and clarity. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

I/We Claim:

1. A system for delivering a prosthesis to a targeted site comprising

a catheter device sized and configured for introduction to a targeted site in a hollow body organ or blood vessel, the catheter device including

a shaft sized and configured to carry the prosthesis a during introduction of the catheter device,

a first release mechanisms coupled to the prosthesis to secure at least one region of the prosthesis to the catheter shaft, and a first actuator to operate the first release mechanism, and

a second release mechanism coupled to the prosthesis in cooperation with the first release mechanism to prevent full release of the at least one region of the at least one region of the prosthesis from the catheter shaft after actuation of the first actuator, whereby actuation of the first actuator partially releases the at least one region of the prosthesis from the catheter shaft at the targeted site without fully releasing the at least one region from the catheter shaft, and a second actuator to operate the second release mechanism to fully release the at least one region of the prosthesis from the catheter shaft, and

a fastening device sized and configured for introduction to the targeted site in the hollow body organ or blood vessel occupied by the catheter device, the fastening device including an actuator to deploy a fastener in the at least one region of the prosthesis after actuation of the first release mechanism and before actuation of the second release mechanism.

2. A system according to claim 1

wherein the second release mechanism comprises at least one stabilizing arm depending from the catheter shaft.

3. A system according to claim 1

wherein the first release mechanism comprises a suture or filament or wire.

4. A system according to claim 1

further including a guide tube for guiding introduction of the fastening device.

5. A system according to claim 4

wherein the guide tube include a mechanism for remotely deflecting the guide tube.

6. A system according to claim 1

further including an interlock mechanism to prevent actuation of the second release mechanism without prior actuation of the first release mechanism.

7. A system according to claim 1

further including a third release mechanism coupled to the prosthesis to release a second region of the prosthesis from the catheter shaft and a third actuator to operate the third release mechanism.

8. A method comprising

positioning a deployment catheter at a targeted site in a hollow body organ or blood vessel, the deployment catheter carrying an expandable endovascular prosthesis,

actuating a first release mechanism on the deployment catheter to allow at least some expansion of at least one region of the prosthesis at the targeted site without fully releasing the one region of the prosthesis from the deployment catheter,

after actuating the first release mechanism, applying a fastener to fasten the at least one region of the prosthesis to the targeted site, and

after applying the fastener, actuating a second release mechanism on the deployment catheter to fully release the at least one region of the prosthesis from the deployment catheter.

9. A method according to claim 8

further comprising, after actuating the first release mechanism but before applying the fastener, adjusting a position of the deployment catheter either longitudinally and/or rotationally.

10. A method according to claim 8

wherein applying a fastener includes deploying a second catheter that includes a fastener deployment mechanism.

11. A method according to claim 10

wherein deploying the second catheter includes use of a guide tube through which the second catheter is introduced.

12. A method according to claim 8

wherein the second release mechanism can be actuated only after actuation of the first release mechanism.

13. A system comprising

a longitudinally compliant prosthesis having a proximal end and a distal end,

a catheter device sized and configured for introduction to a targeted site in a hollow body organ or blood vessel, the first catheter device including

a shaft sized and configured to carry the prosthesis during introduction of the catheter device,

a first release mechanisms coupled to a proximal end of the prosthesis to secure the proximal end the prosthesis to the catheter shaft, and a first actuator to operate the first release mechanism,

a second release mechanism coupled to the proximal end of the prosthesis in cooperation with the first release mechanism to prevent full release of the proximal end of the prosthesis from the catheter shaft after actuation of the first actuator, whereby actuation of the first actuator partially releases the proximal end prosthesis from the catheter shaft at the targeted site without fully releasing the proximal end of the

prosthesis from the catheter shaft, and a second actuator to operate the second release mechanism to fully release the proximal end of the prosthesis from the catheter shaft, and

a third release mechamism coupled to the distal end of the prosthesis independent of the first and second release mechanisms and a third actuator to operate the third release mechanism to fully release the distal end of the prosthesis from the catheter shaft, and

a fastening device sized and configured for introduction to the targeted site in the hollow body organ or blood vessel occupied by the catheter device, the fastening device including an actuator to deploy a fastener in the proximal end of the prosthesis after actuation of the first release mechanism and before actuation of the second and third release mechanisms.

14. A system according to claim 13

wherein the second release mechanism comprises at least one stabilizing arm depending from the catheter shaft.

15. A system according to claim 13

wherein the first release mechanism comprises a suture or filament or wire.

16. A system according to claim 13

further including a guide tube for guiding introduction of the fastening device.

17. A system according to claim 16

wherein the guide tube include a mechanism for remotely deflecting the guide tube.

18. A system according to claim 13

further including an interlock mechanism to prevent actuation of the second release mechanism without prior actuation of the first release mechanism.

19. A method comprising

positioning a deployment catheter at a targeted site

in a hollow body organ or blood vessel, the deployment catheter carrying an expandable endovascular prosthesis,

actuating a first release mechanism on the deployment catheter to allow at least some expansion of the proximal region of the prosthesis at the targeted site without fully releasing the proximal end of the prosthesis from the deployment catheter,

after actuating the first release mechanism, applying a fastener to fasten the proximal end the prosthesis to the targeted site,

after applying the fastener, actuating a second release mechanism on the deployment catheter to fully release the proximal end of the prosthesis from the deployment catheter, and

after applying the fastener, actuating a third release mechanism on the deployment catheter to fully release the distal end of the prosthesis from the deployment catheter.

20. A method according to claim 19

further comprising, after actuating the first release mechanism, but before actuating either the second or third release mechanism, and also before applying the fastener, adjusting a position of the deployment catheter either longitudinally and/or rotationally.

21. A method according to claim 19

wherein the second release mechanism can be actuated only after actuation of the first release mechanism.

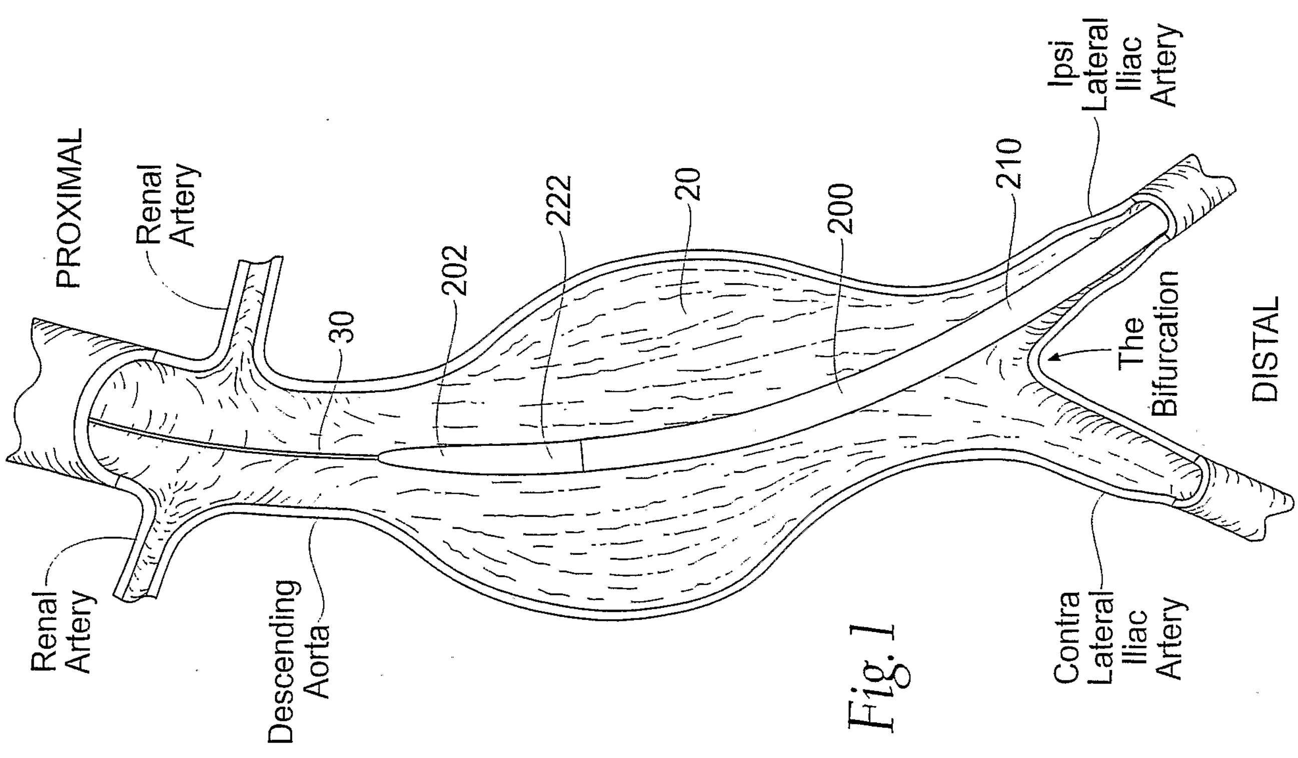
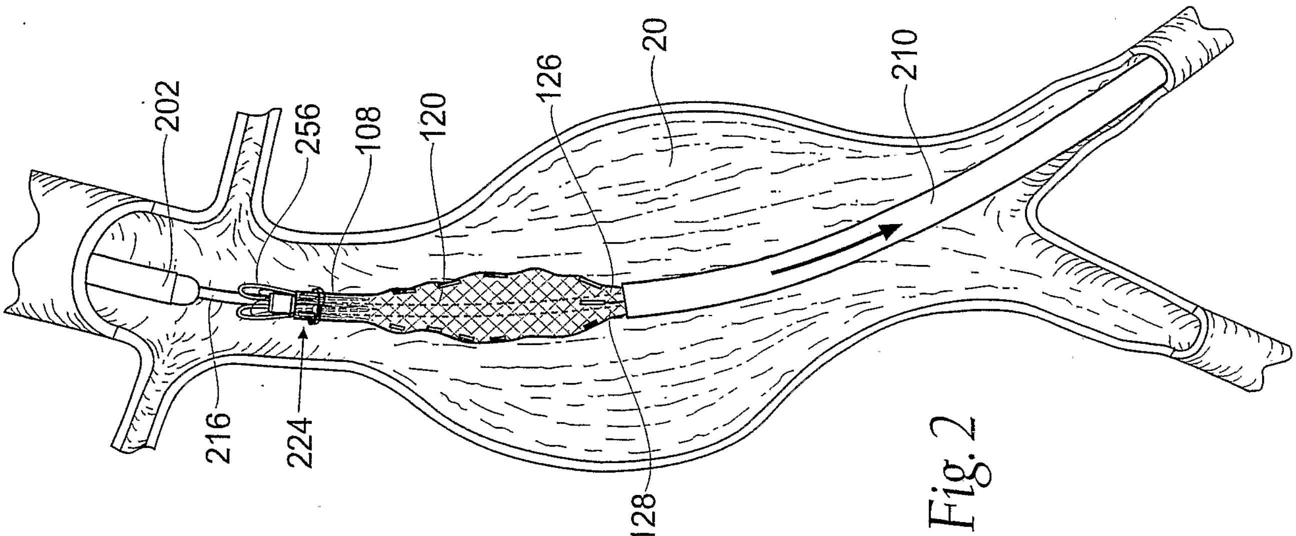

PROXIMAL
Renal Artery
Renal Artery
Descending Aorta
30
202
222
20
200
210
Ipsi Lateral Iliac Artery
The Bifurcation
DISTAL
Contra Lateral Iliac Artery

Fig. 1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256
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216
224
128

Fig. 2

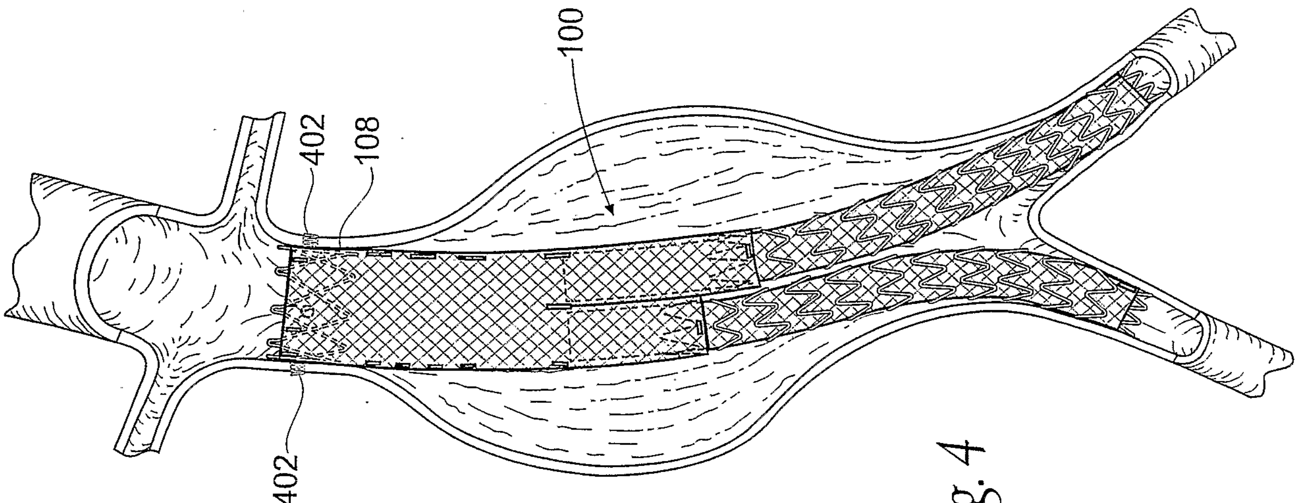


Fig. 4

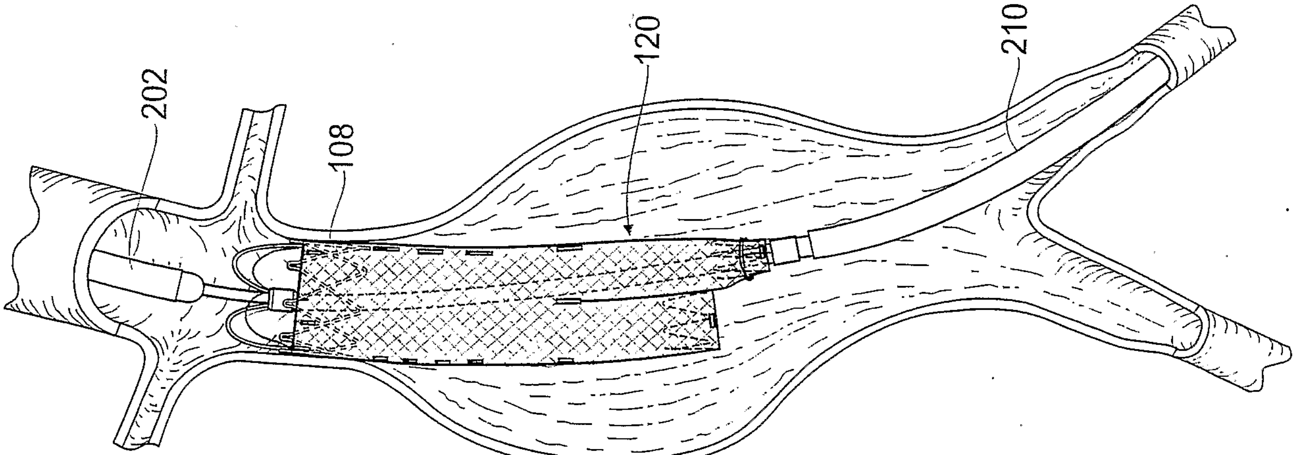


Fig. 3

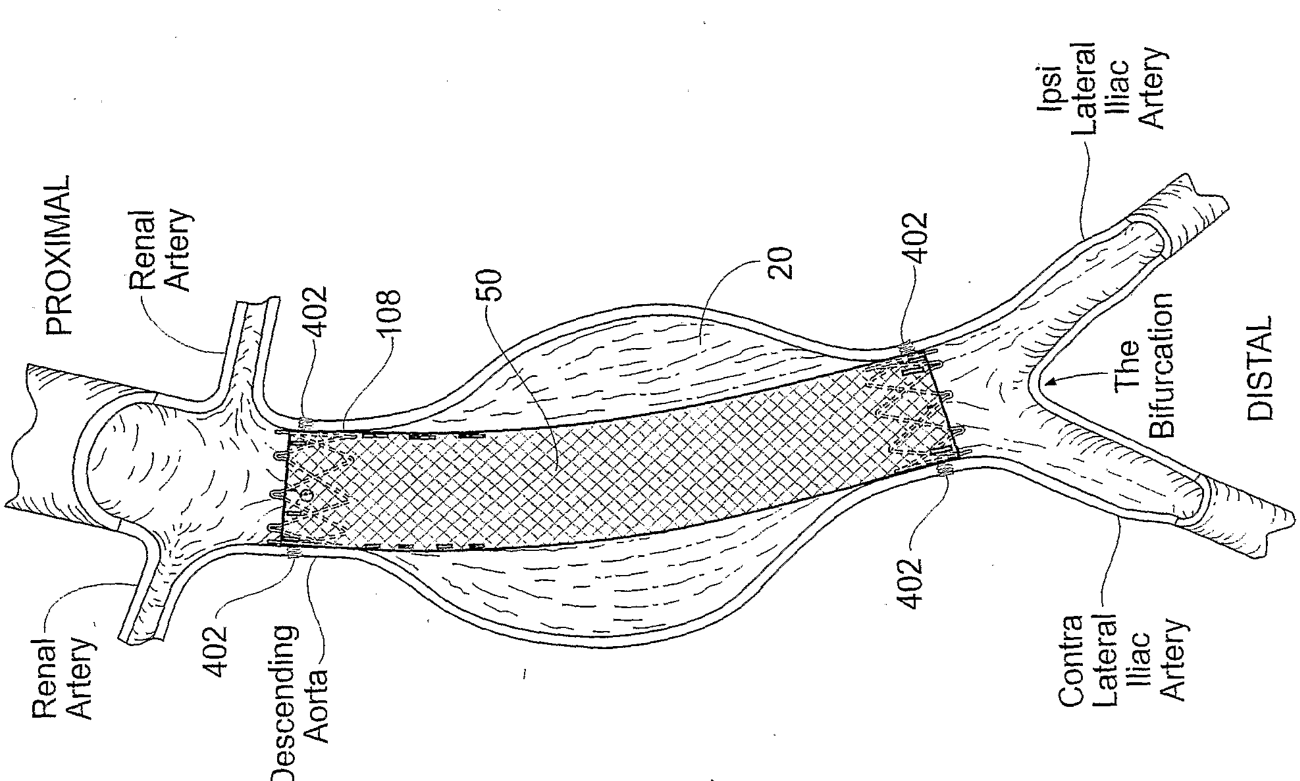

PROXIMAL
Renal Artery
402
108
50
20
402
Ipsi Lateral Iliac Artery
The Bifurcation
DISTAL
Renal Artery
402
Descending Aorta
402
Contra Lateral Iliac Artery

Fig. 5

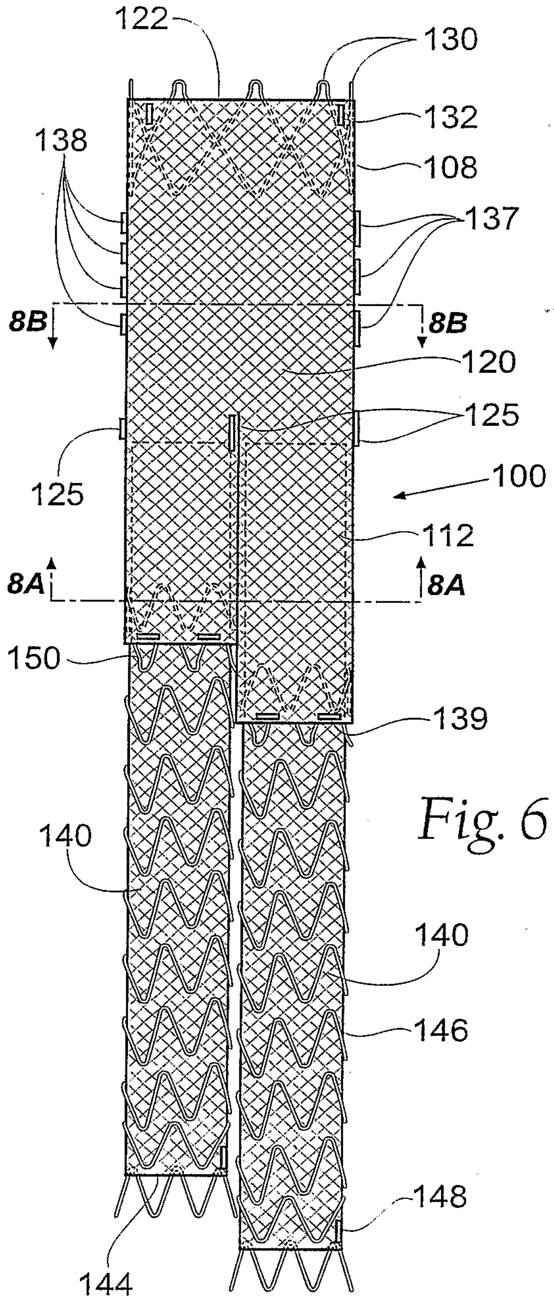
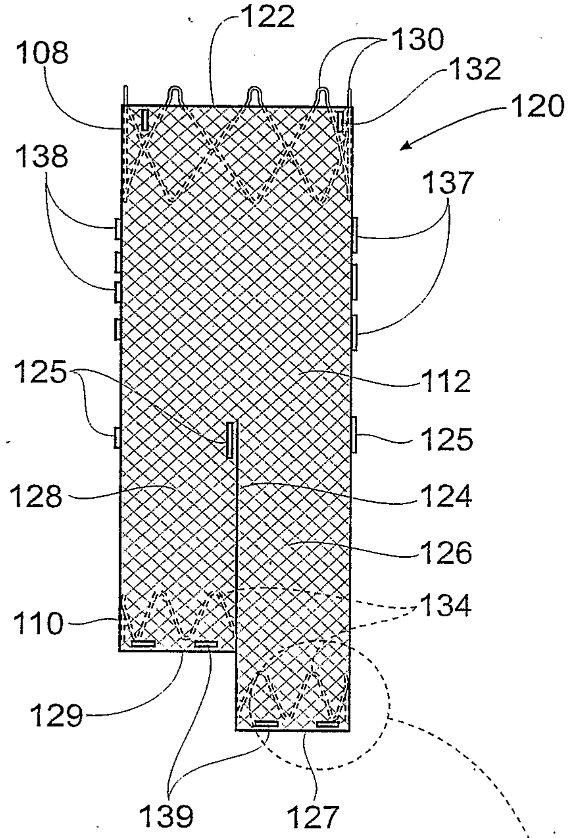


Fig. 6

Fig. 7A



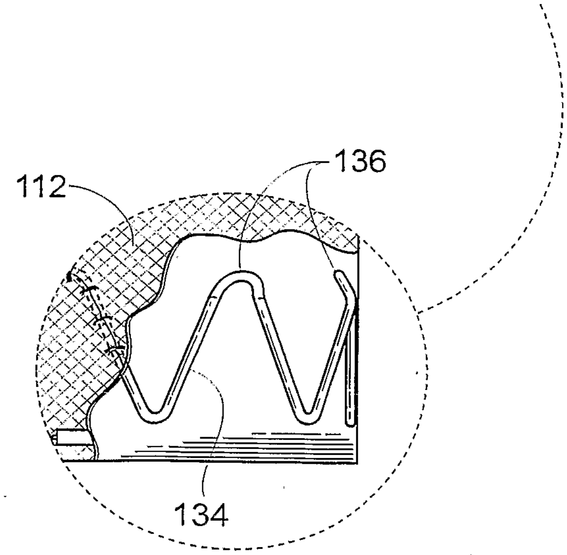
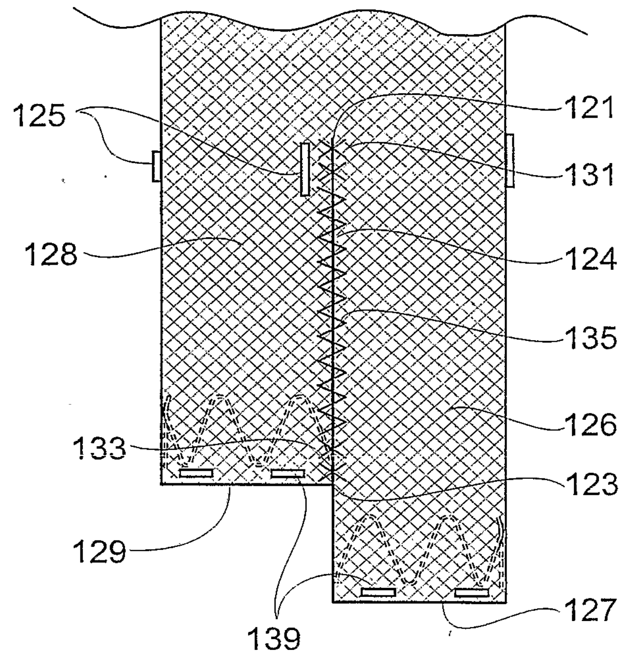


Fig. 7B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127
139

Fig. 7C

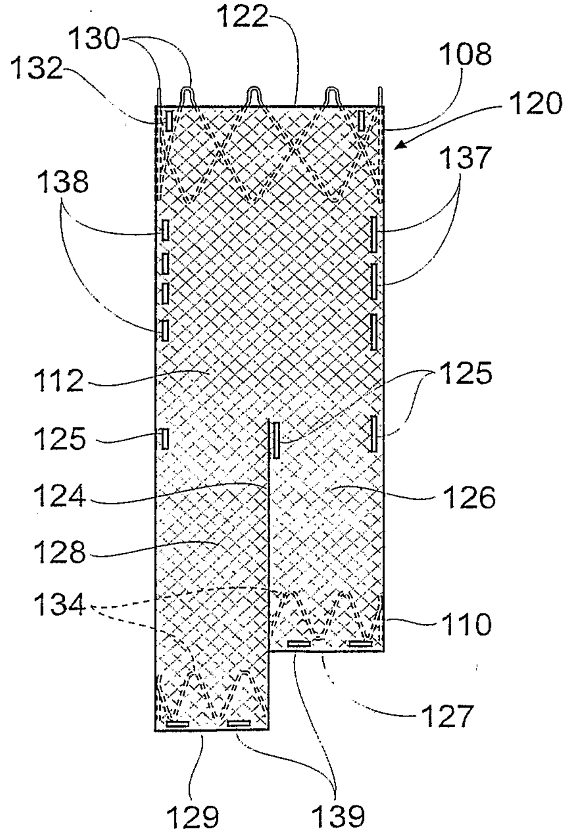
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Fig. 7D

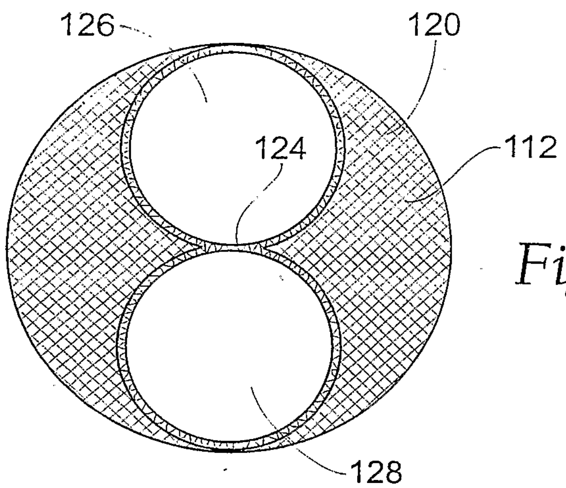

Fig. 8A

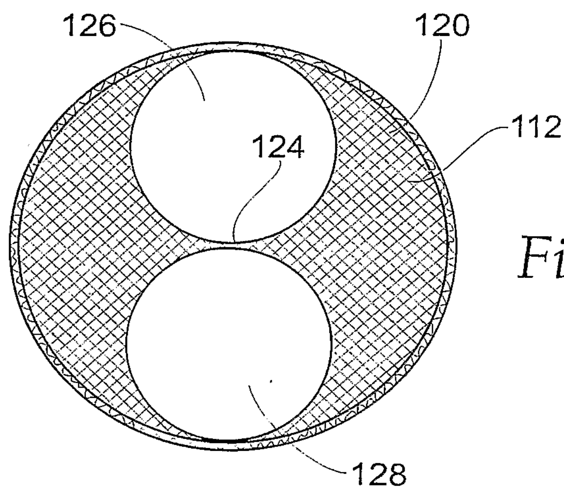

Fig. 8B

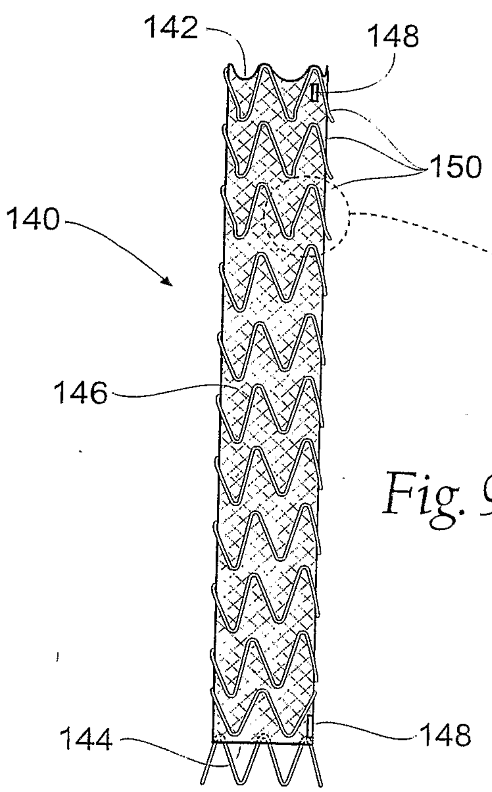

Fig. 9A

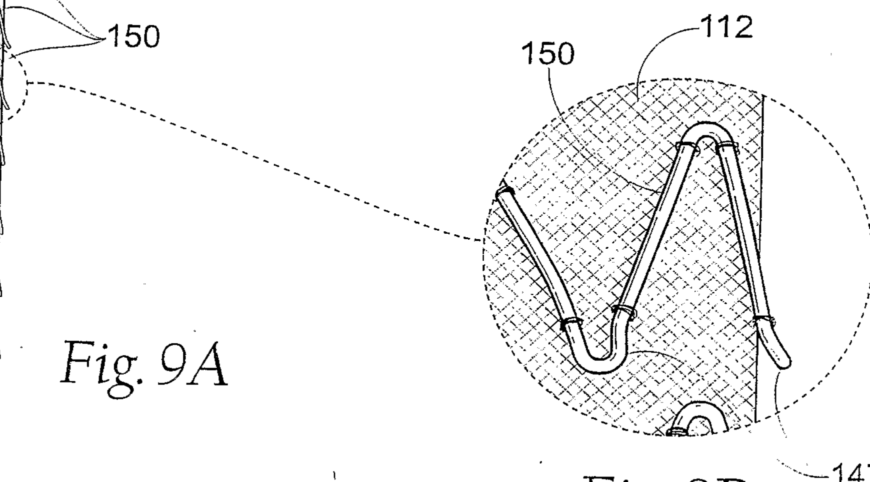

Fig. 9B

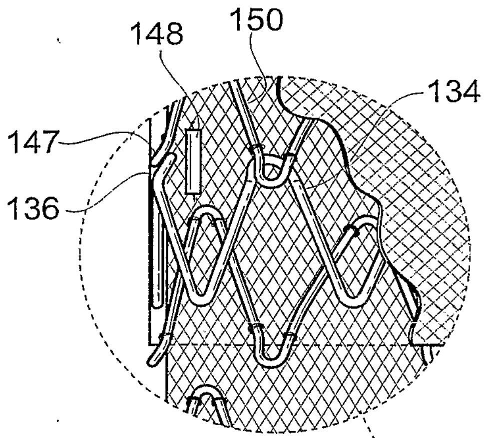
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Fig. 9D

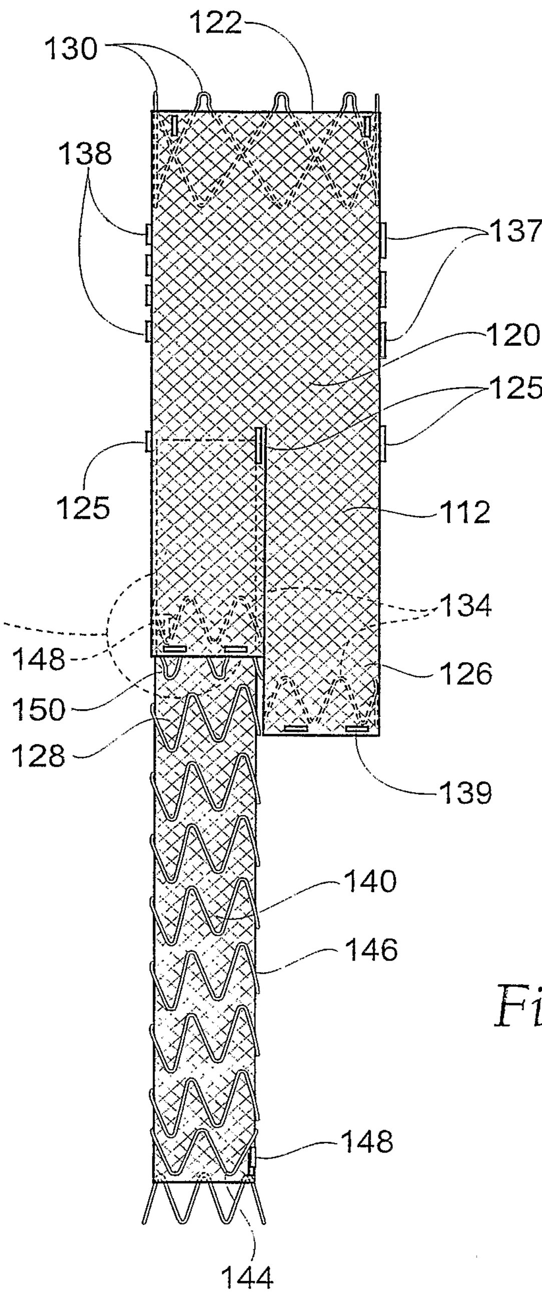
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Fig. 9C

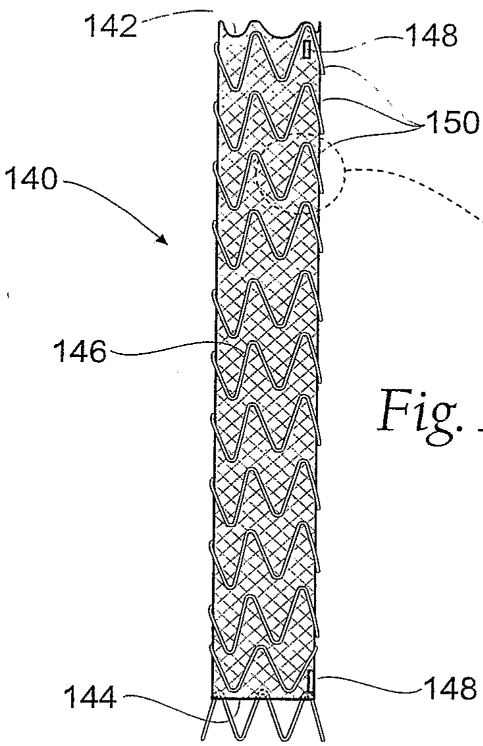


Fig. 10A

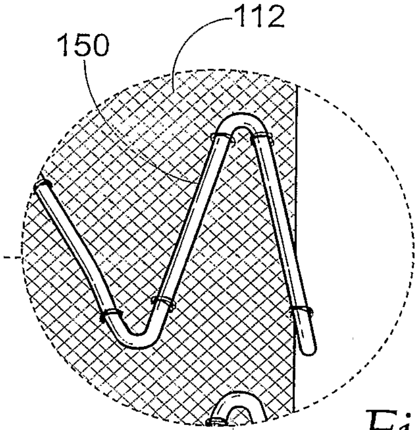


Fig. 10B

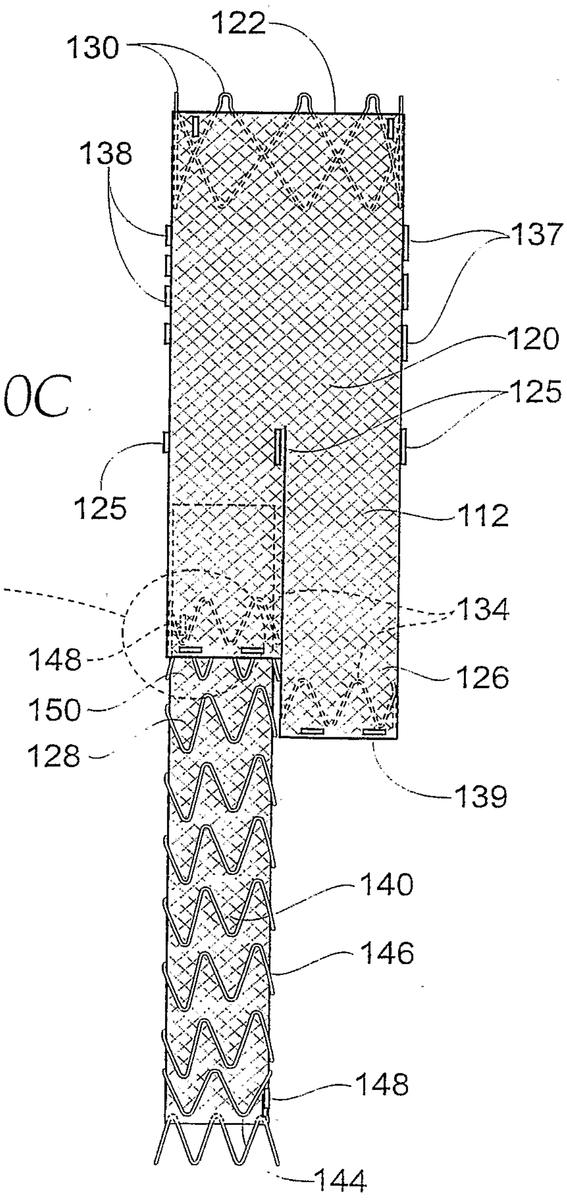


Fig. 10C

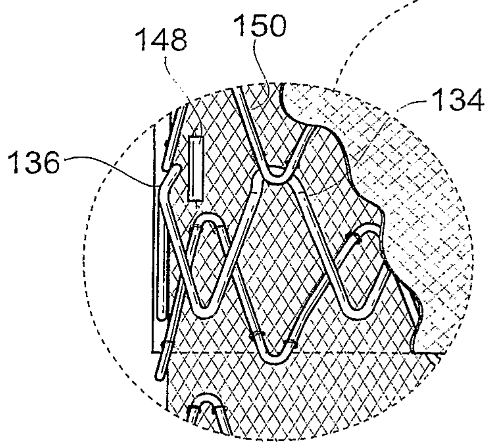
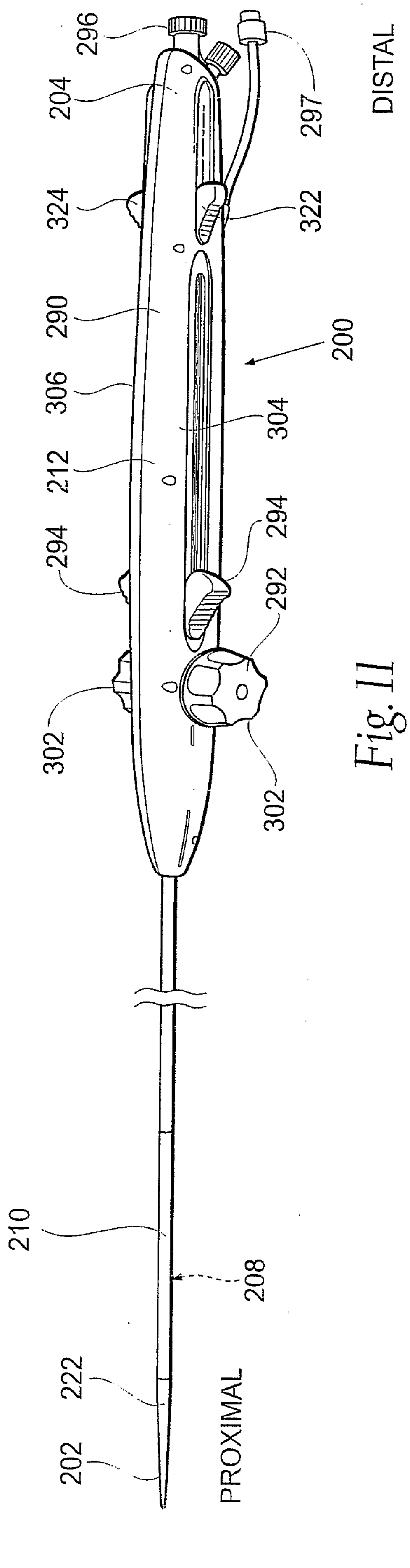


Fig. 10D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202
PROXIMAL

Fig. 11

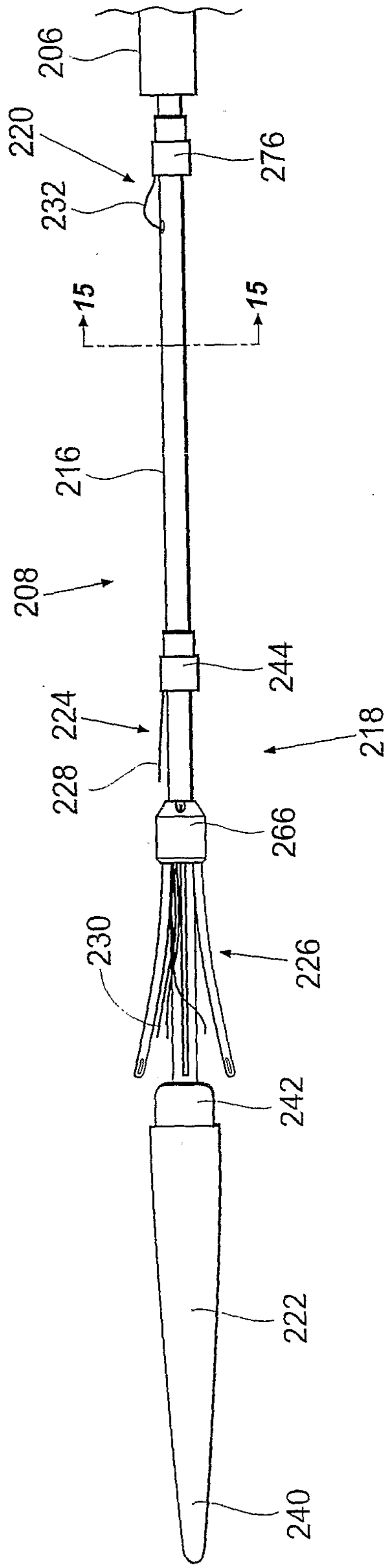
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Fig. 12

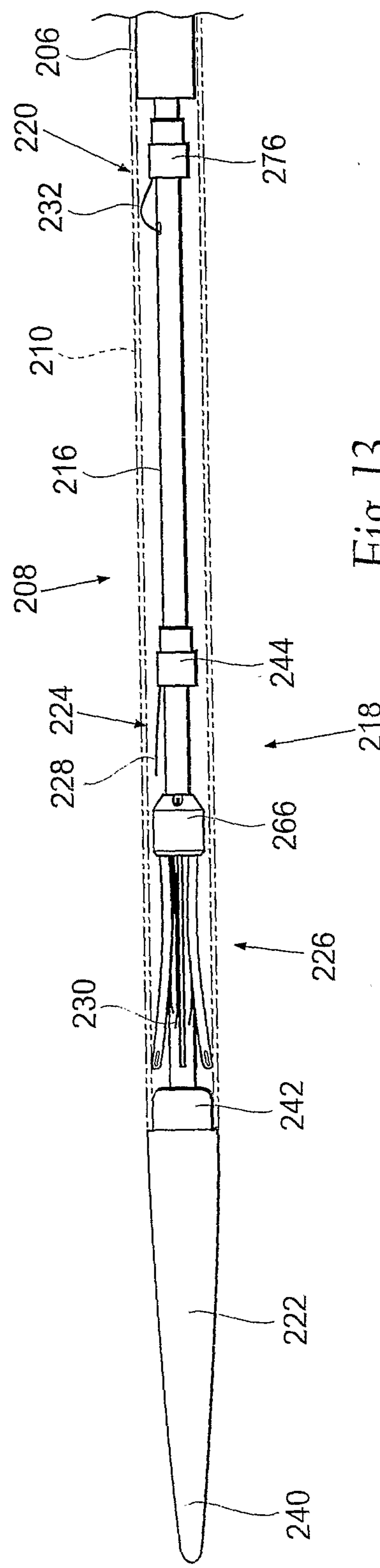
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Fig. 13

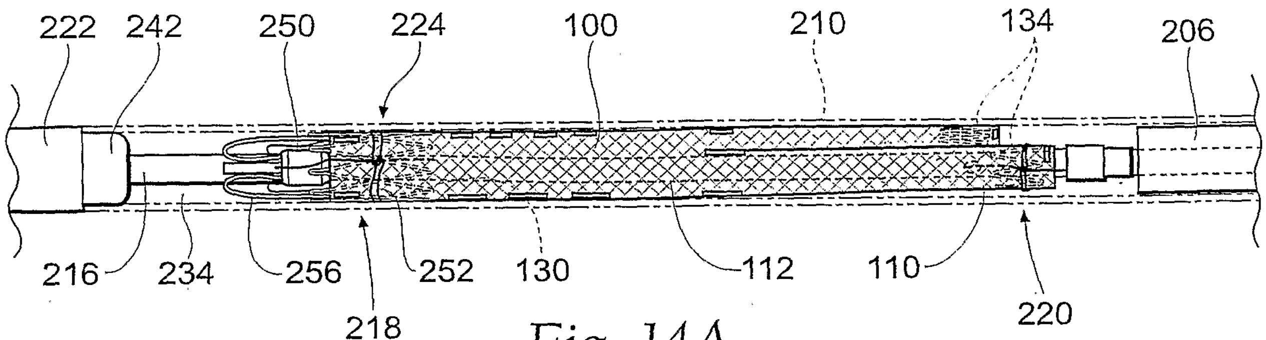

Fig. 14A

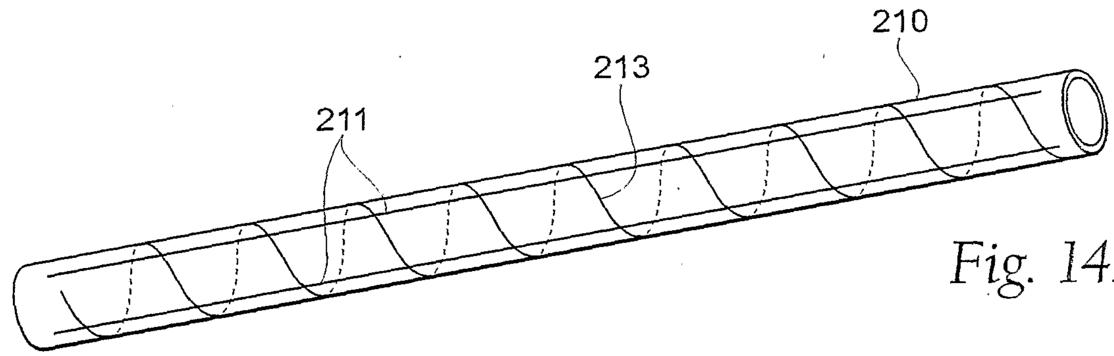

Fig. 14B

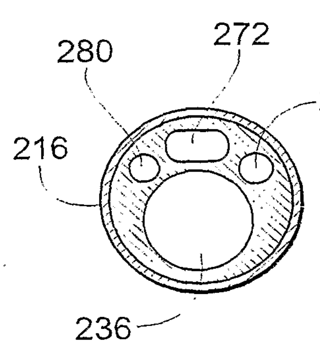

Fig. 15

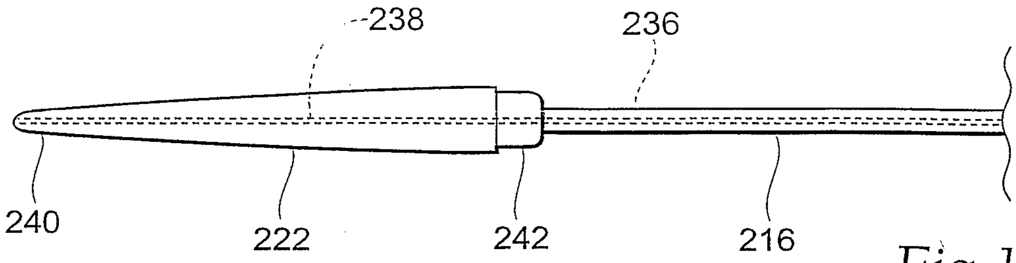

Fig. 16

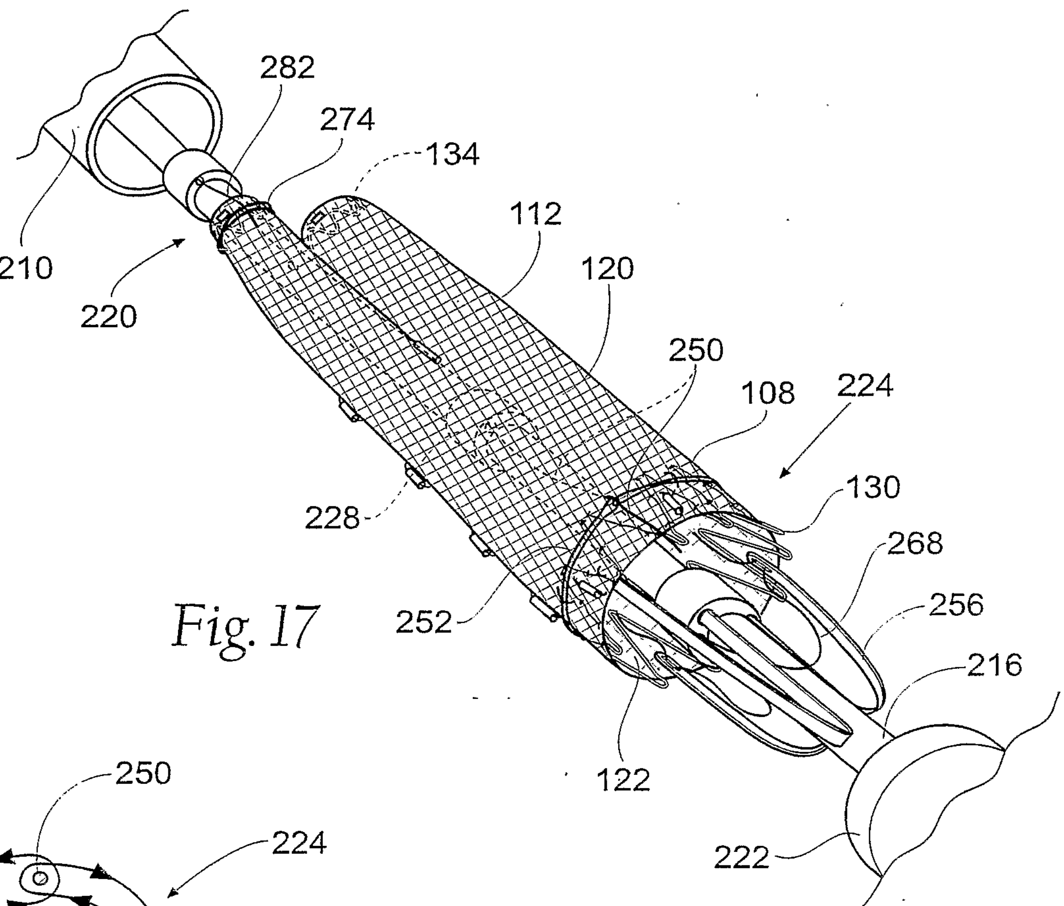

Fig. 17

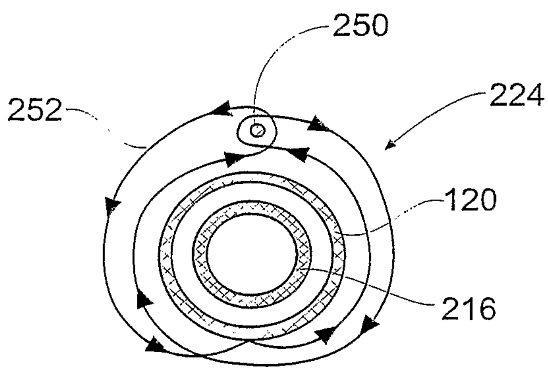

Fig. 18A

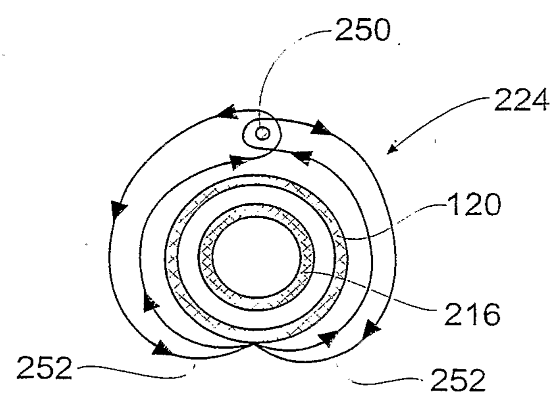

Fig. 18B

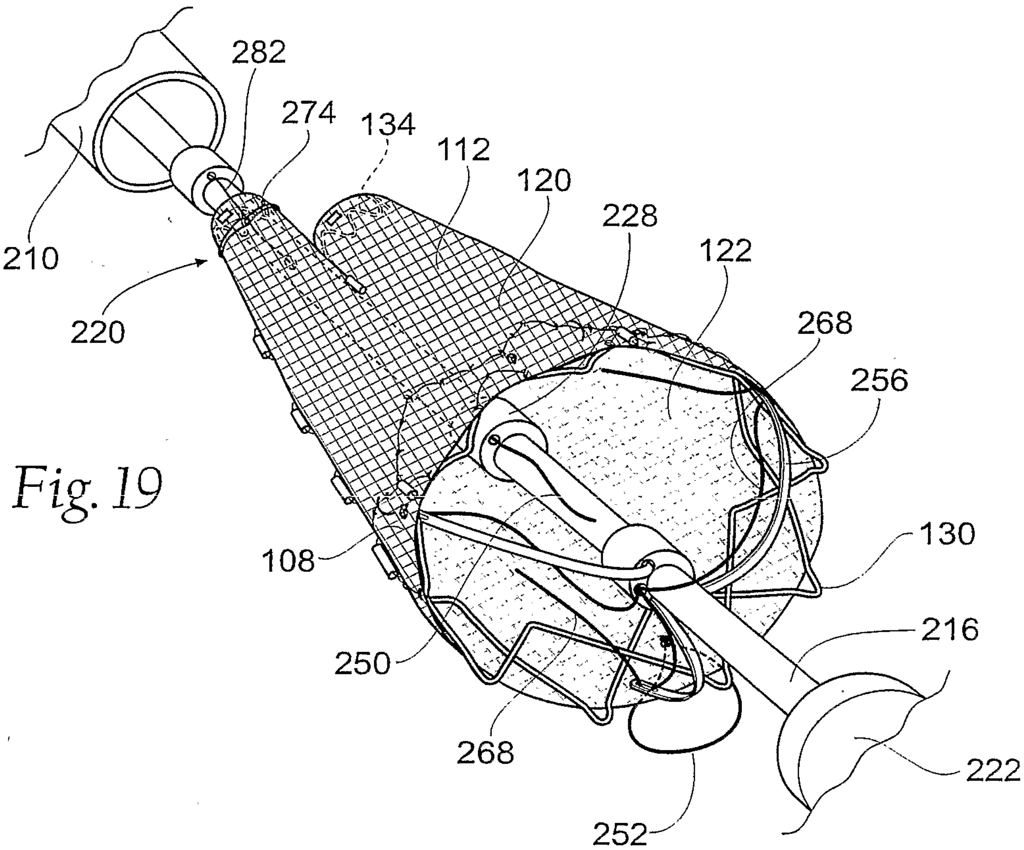
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Fig. 19

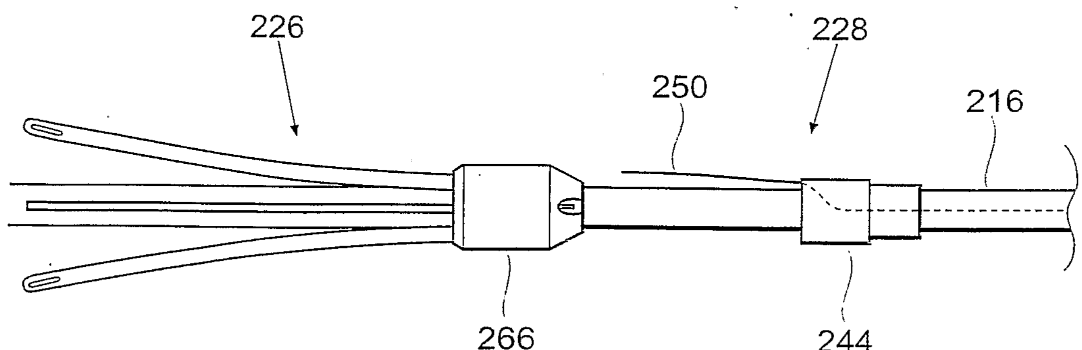
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Fig. 20

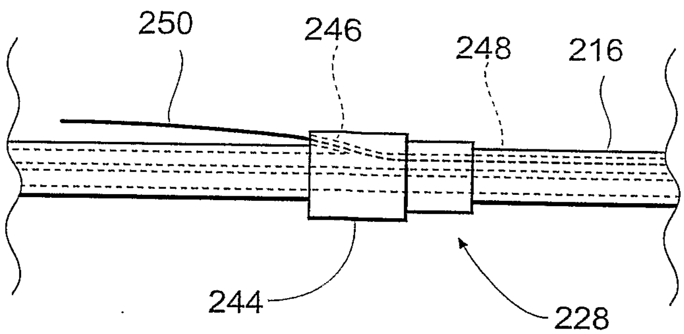


Fig. 21

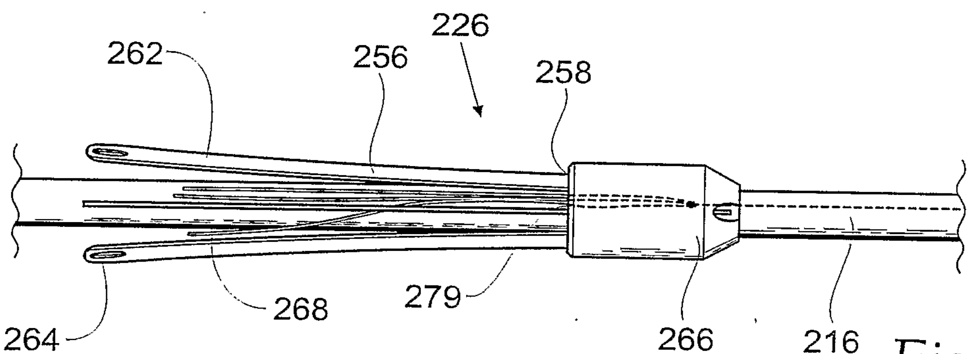


Fig. 22

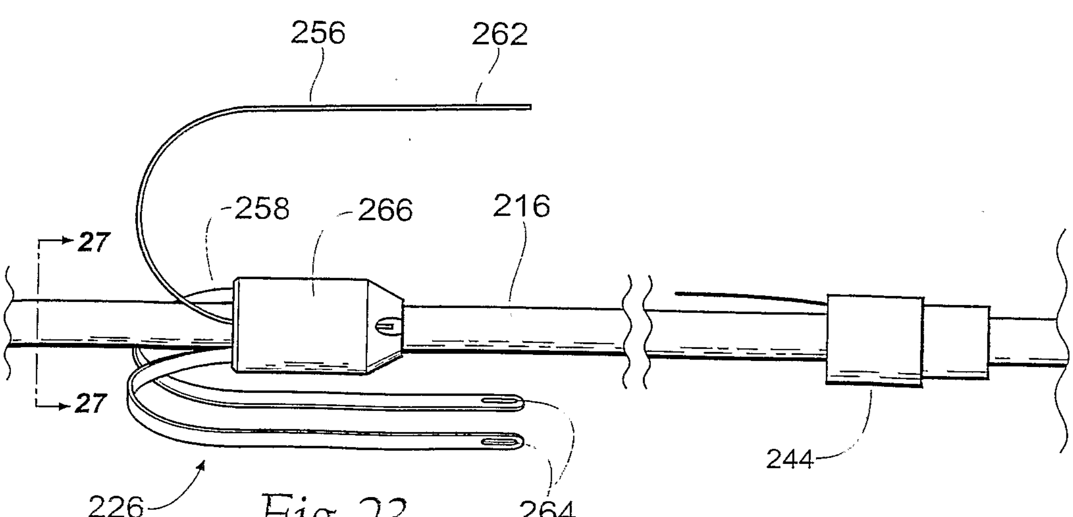
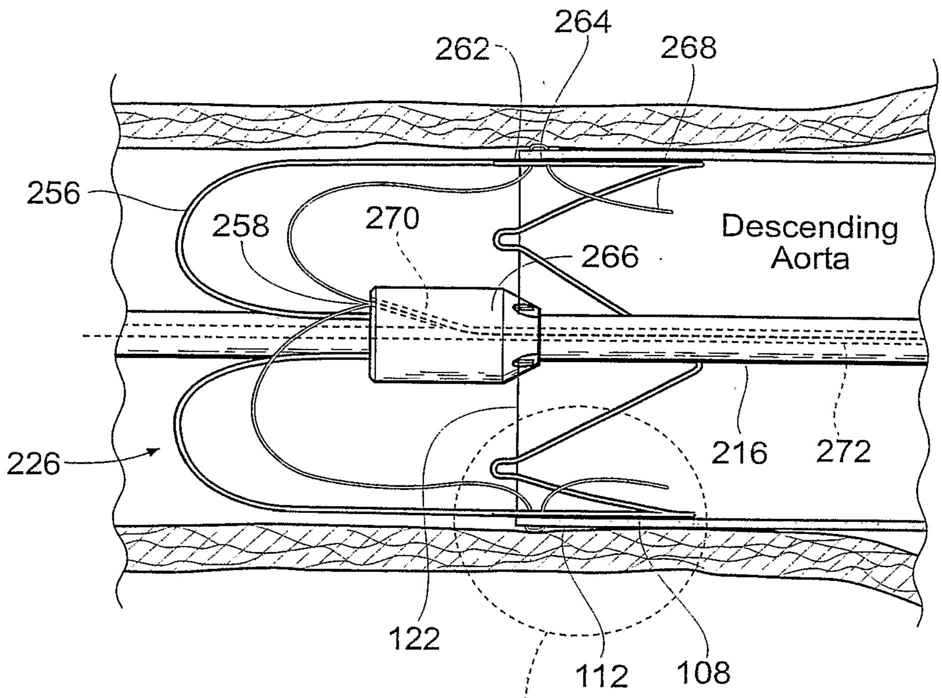


Fig. 23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264
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256
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270
266
Descending
Aorta
226
216
272
122
112
108

Fig. 24

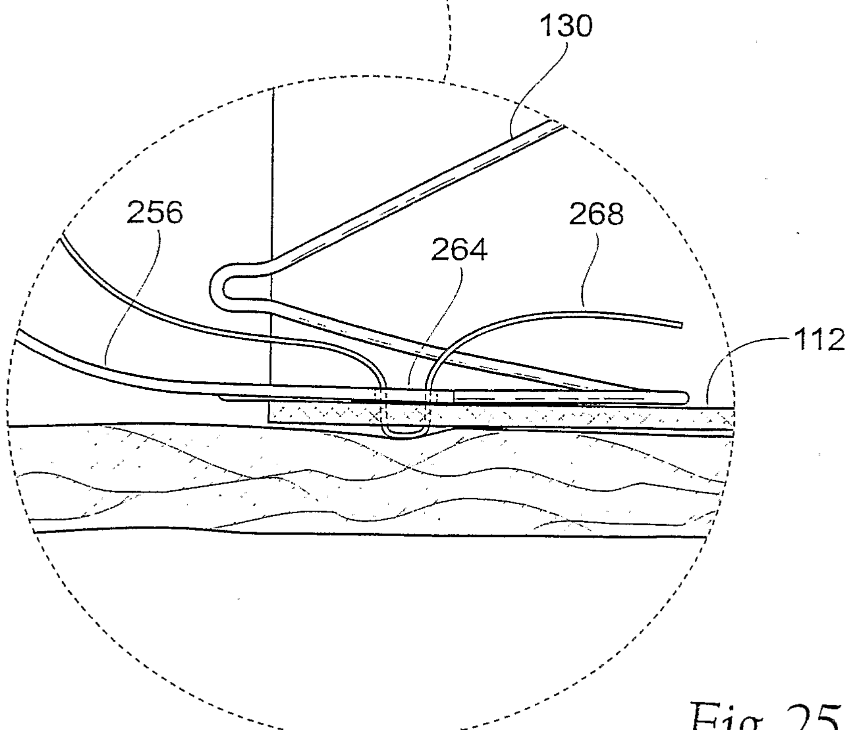
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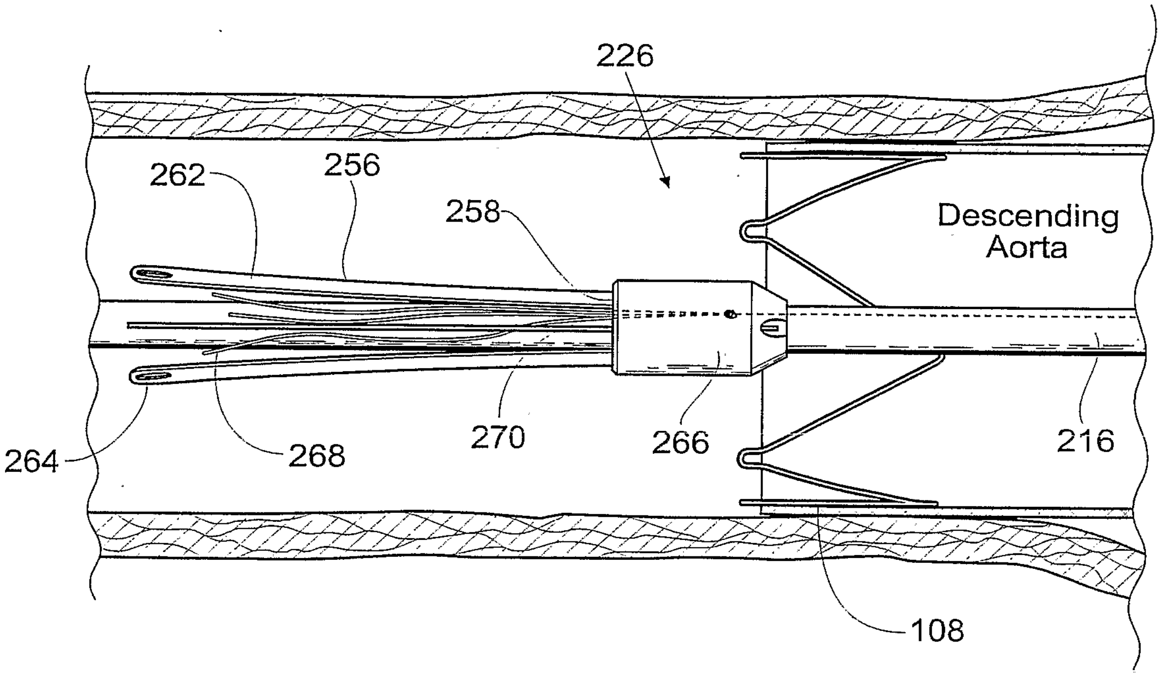
Fig. 25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Descending Aorta
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Fig. 26

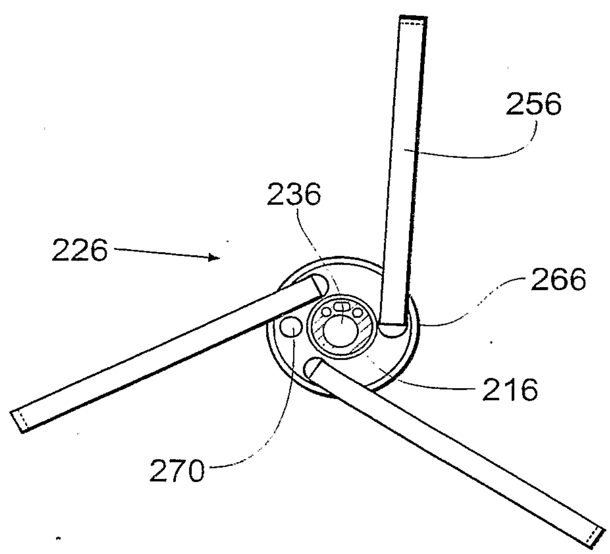
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Fig. 27

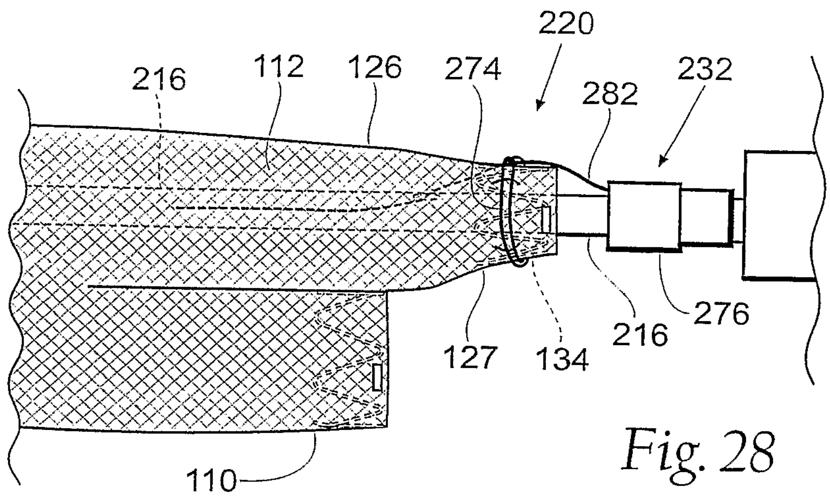

Fig. 28

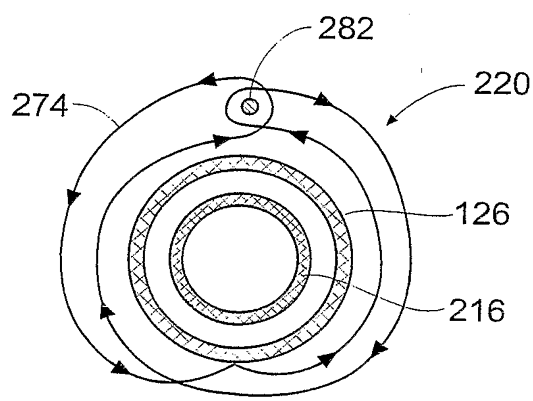

Fig. 29A

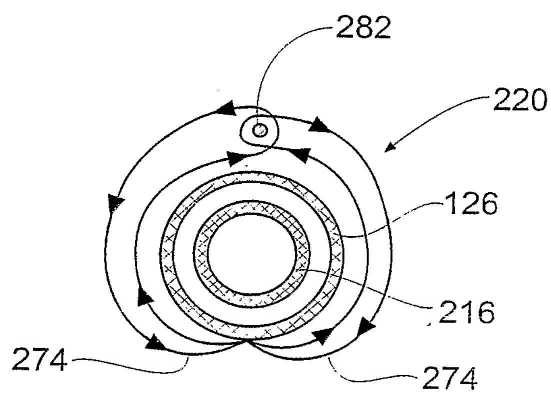

Fig. 29B

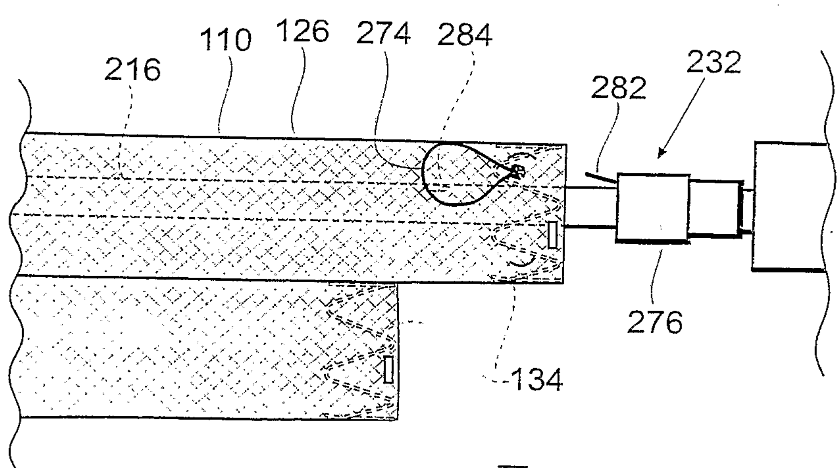

Fig. 30

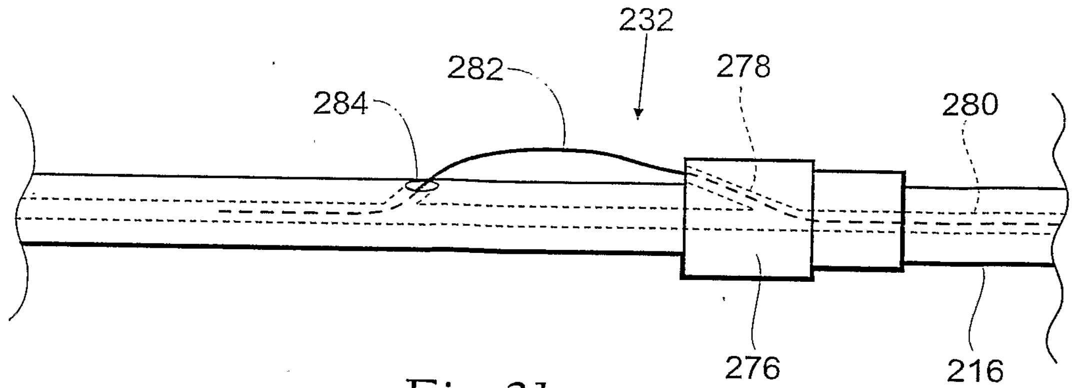

Fig. 31

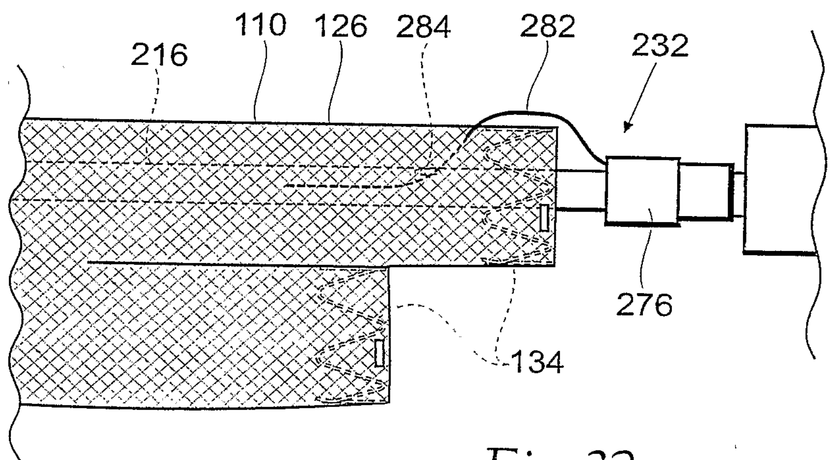

Fig. 32

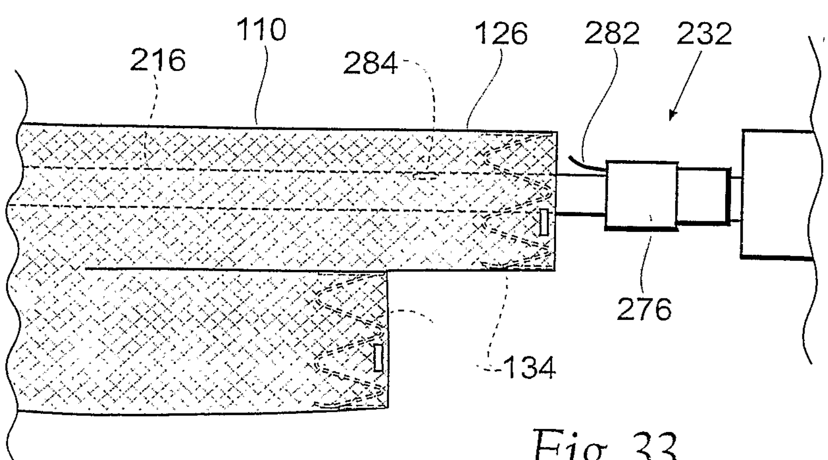

Fig. 33

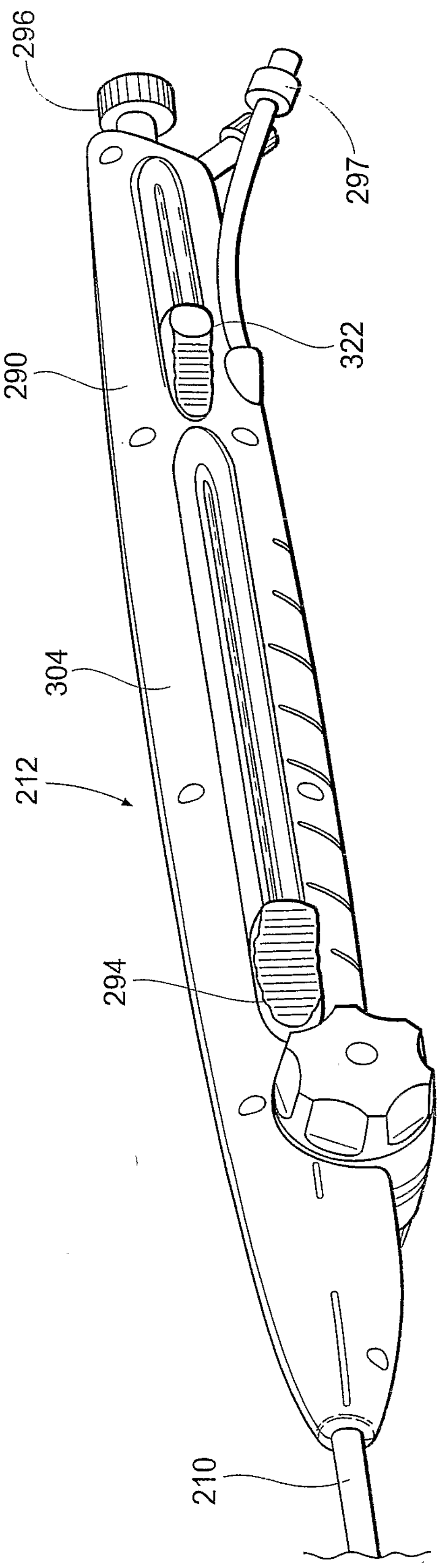
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Fig. 34

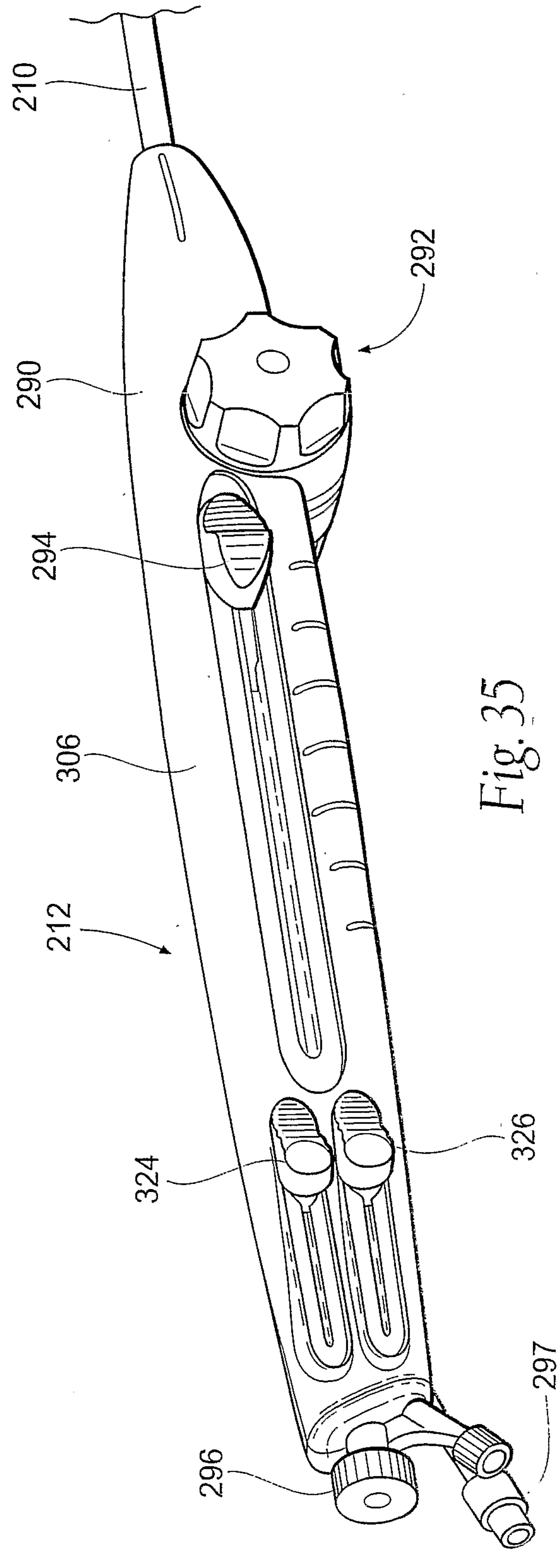
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Fig. 35

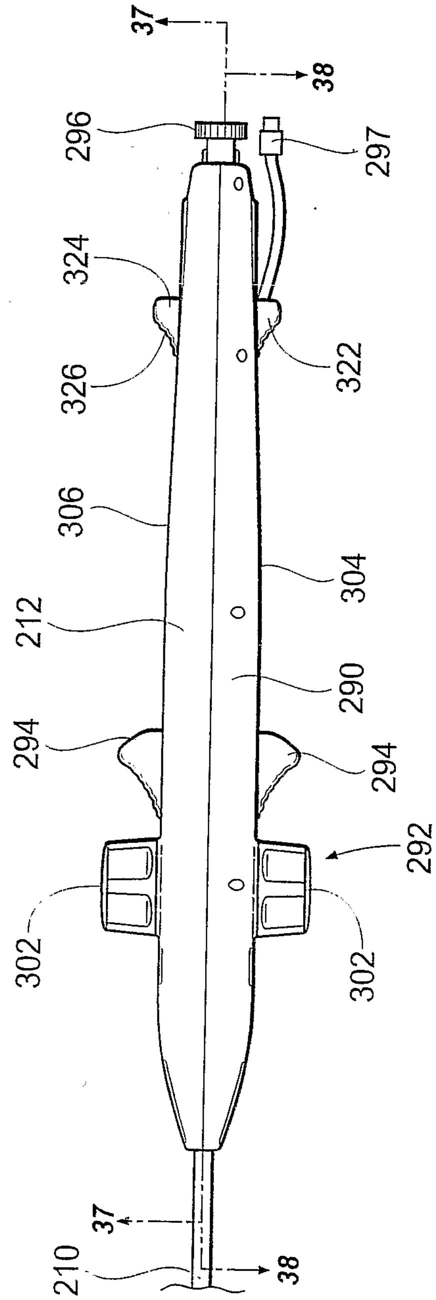
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Fig. 36

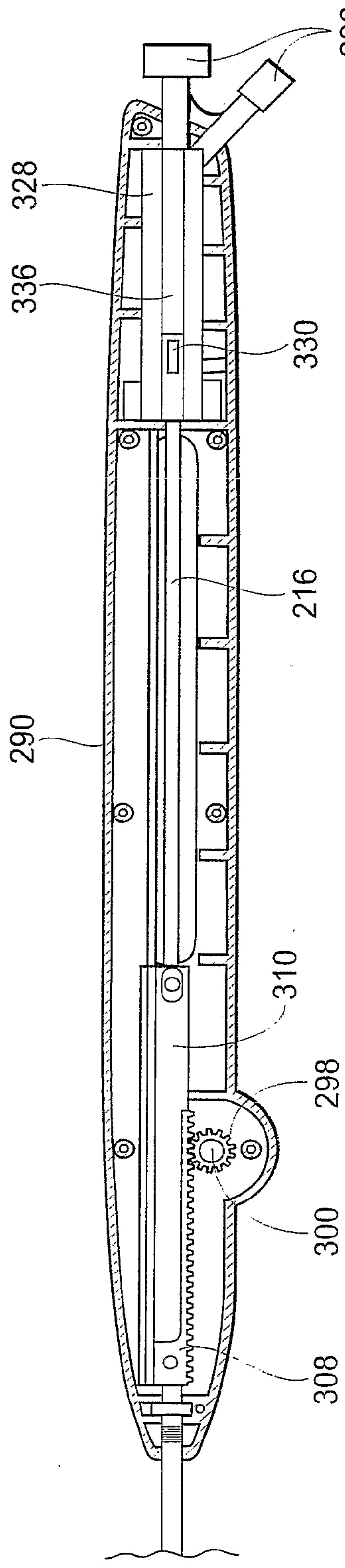
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Fig. 37

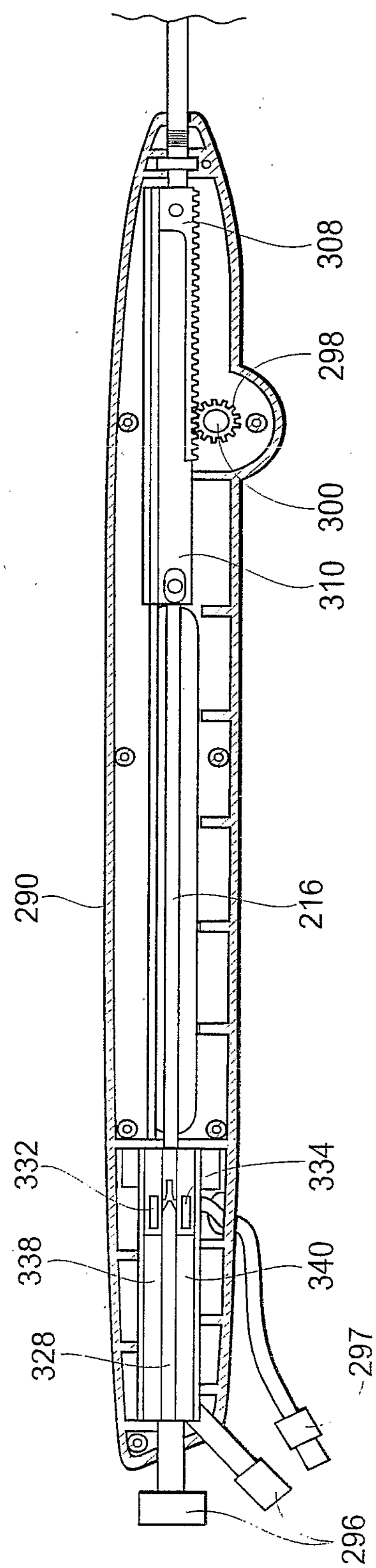
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Fig. 38

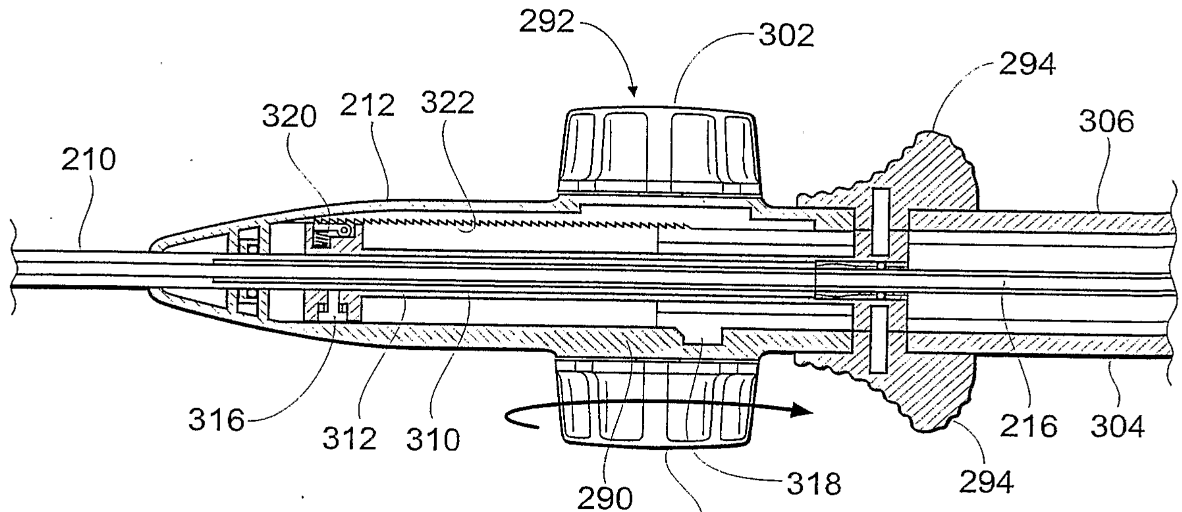
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Fig. 39

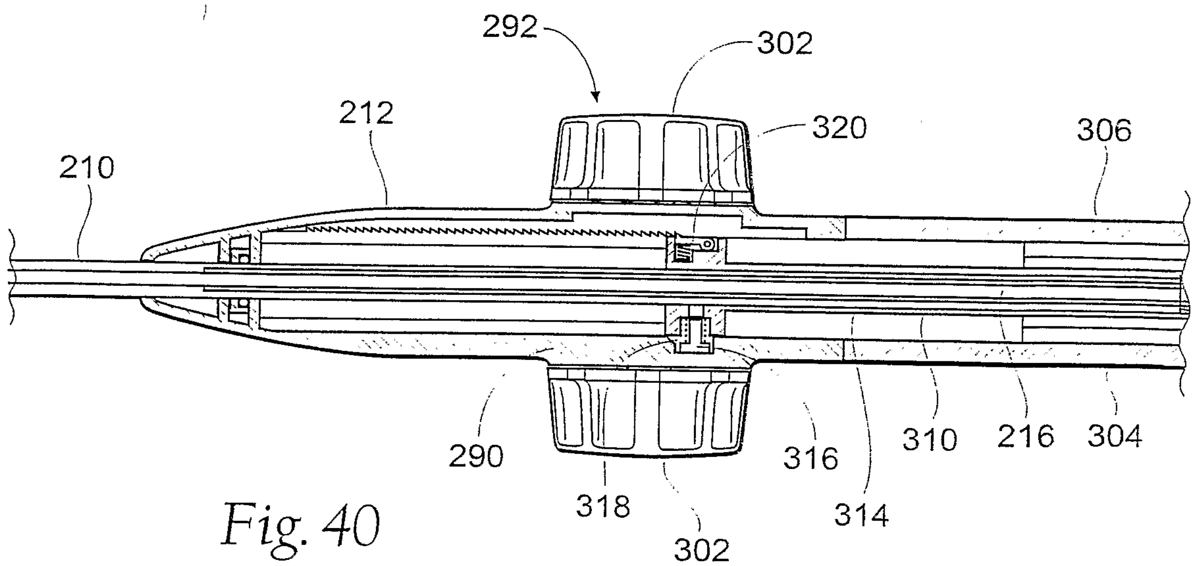
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Fig. 40

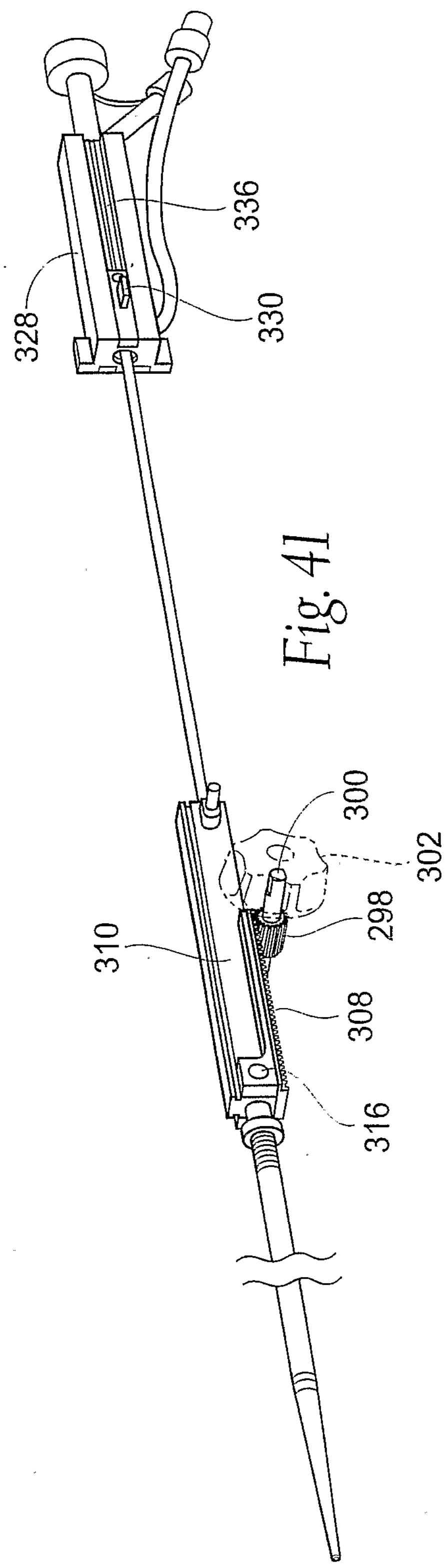


Fig. 41

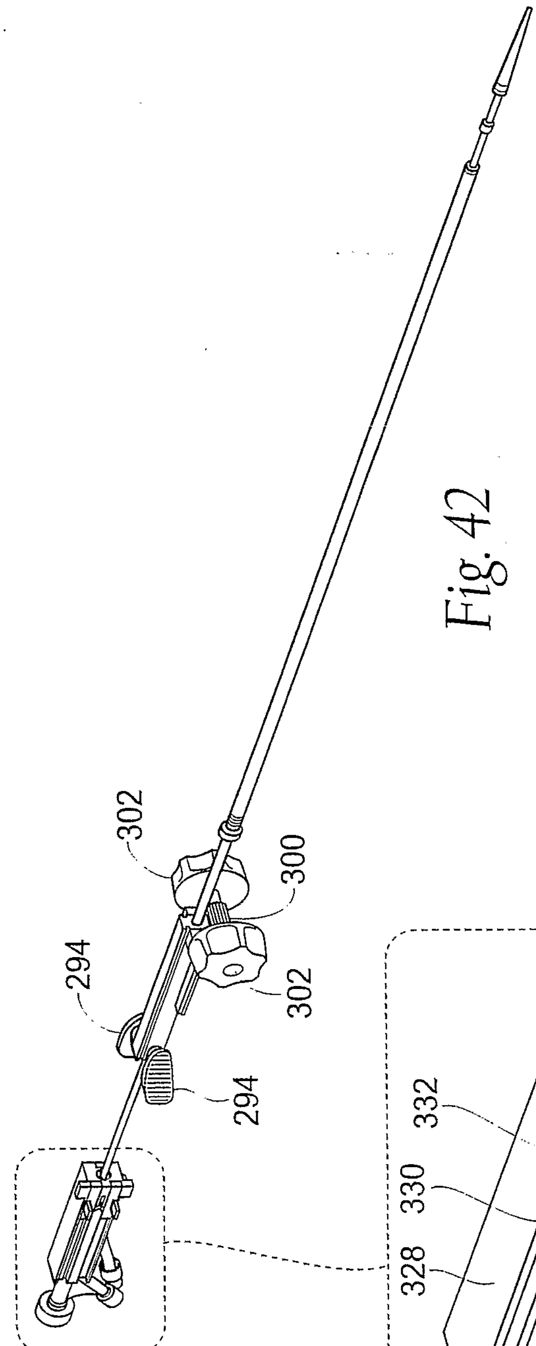


Fig. 42

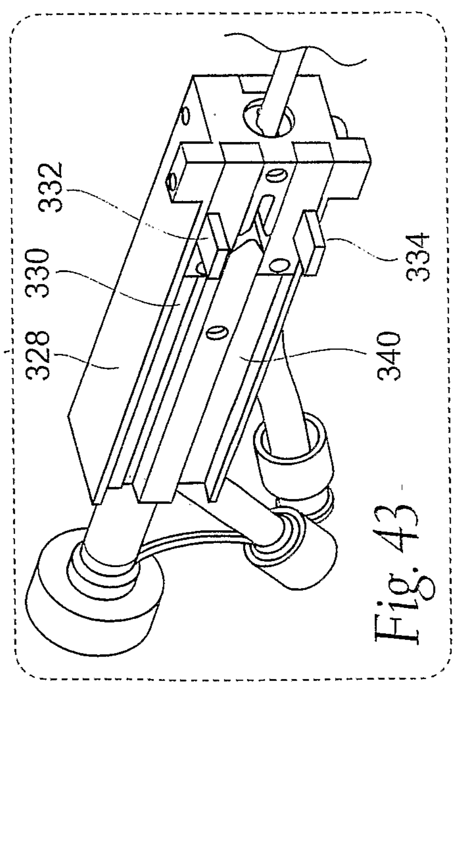


Fig. 43

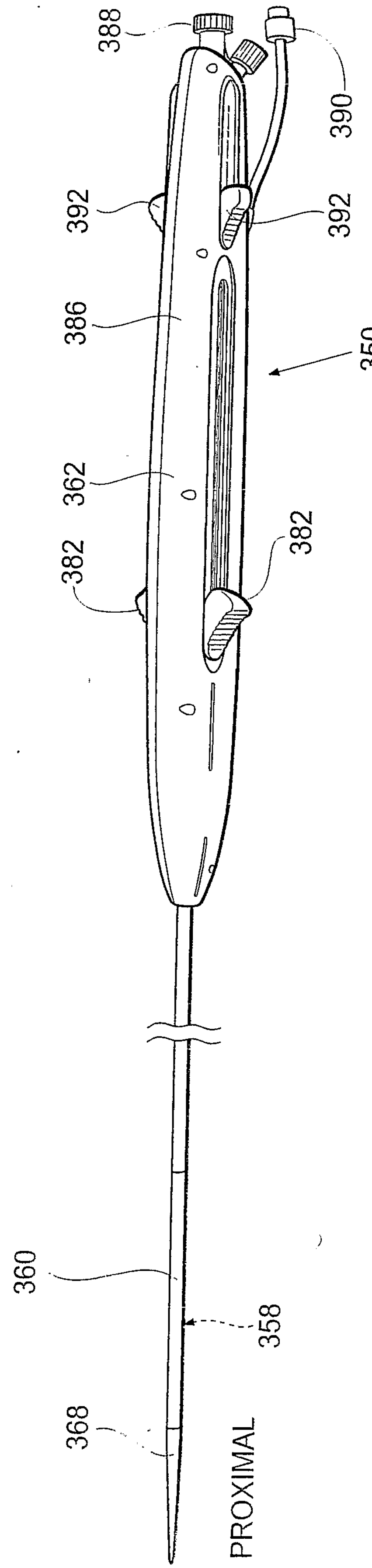


Fig. 44A

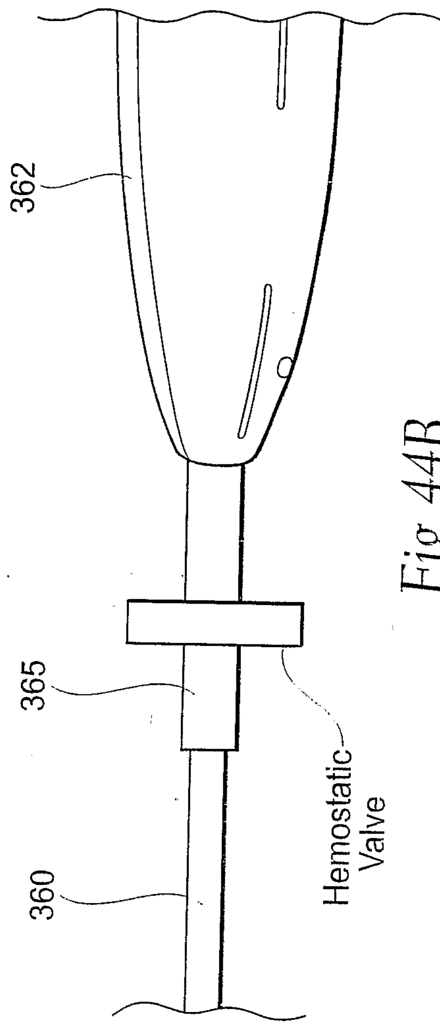


Fig. 44B

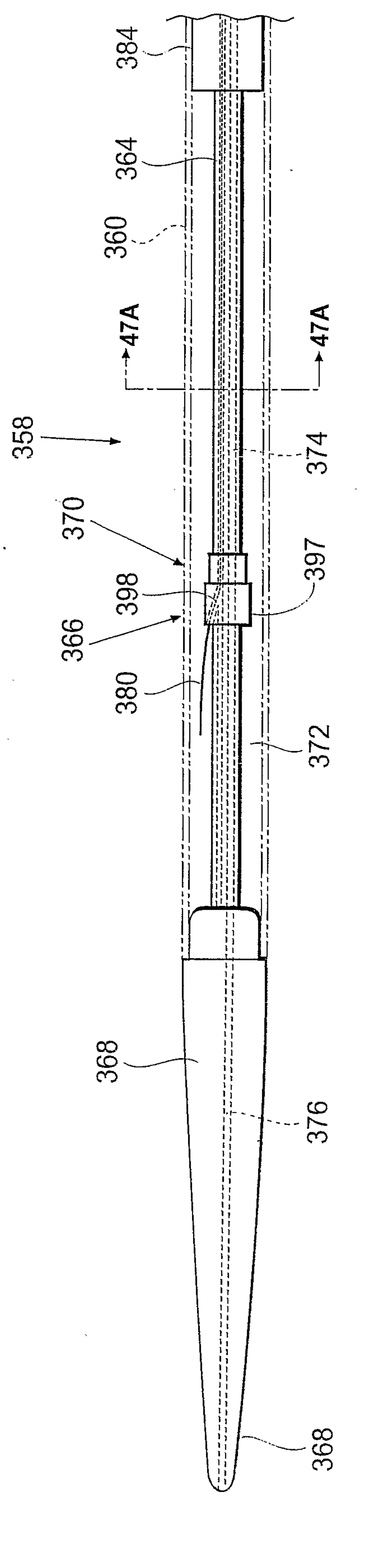


Fig. 45A

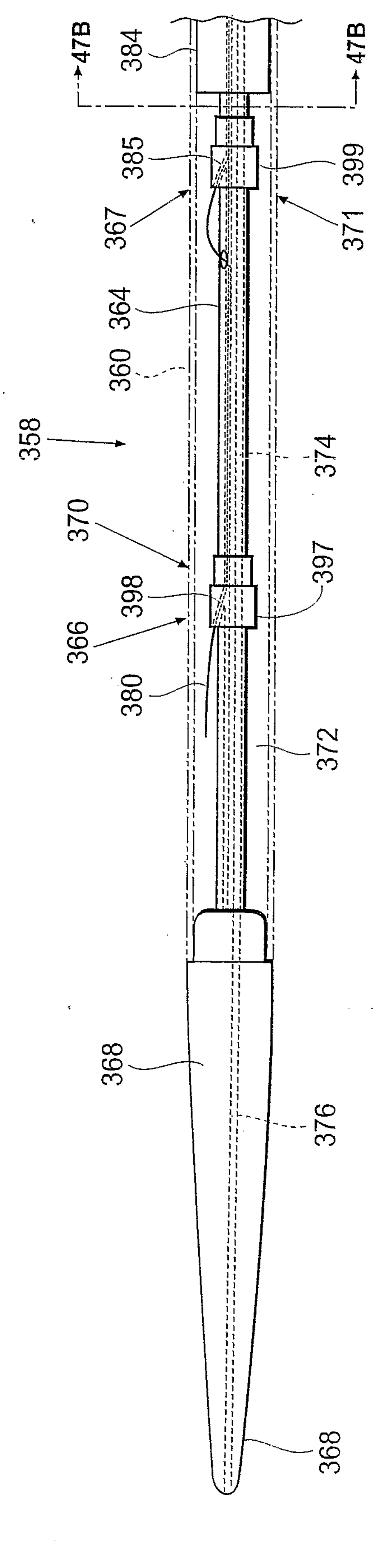


Fig. 45B

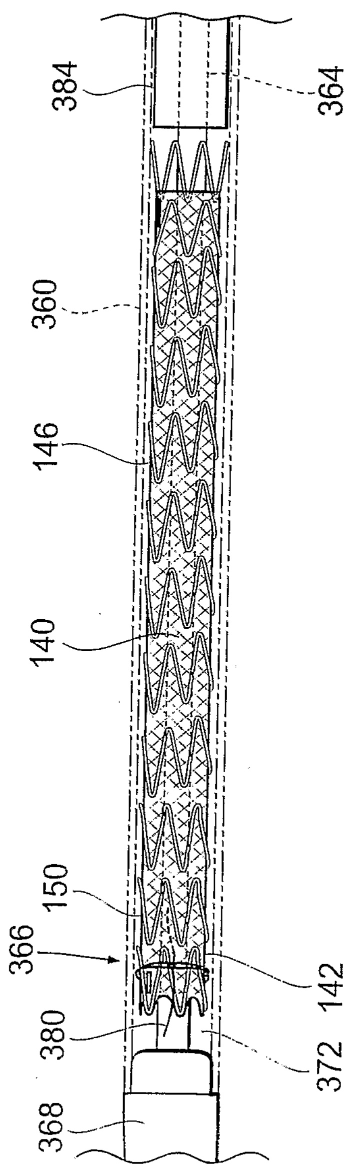


Fig. 46A

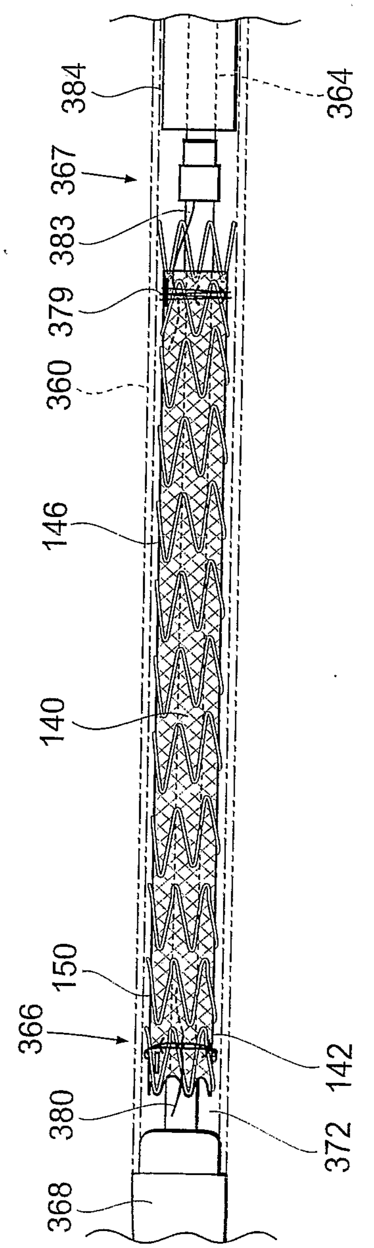


Fig. 46B

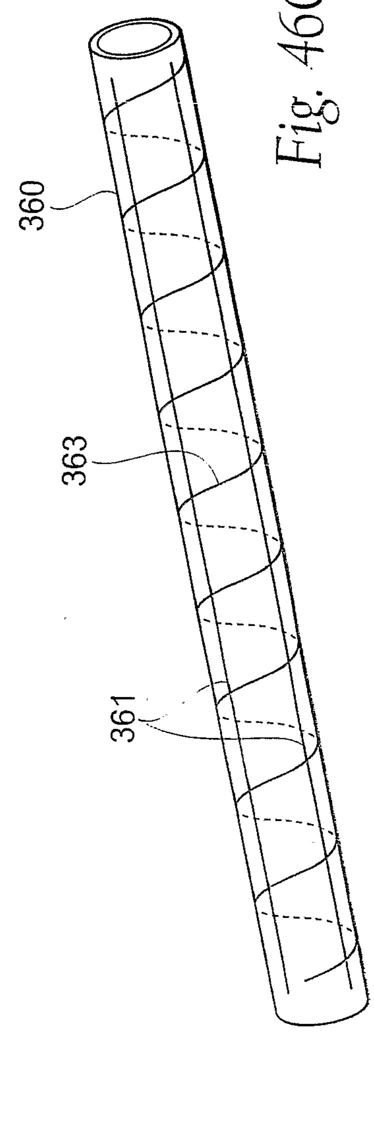


Fig. 46C

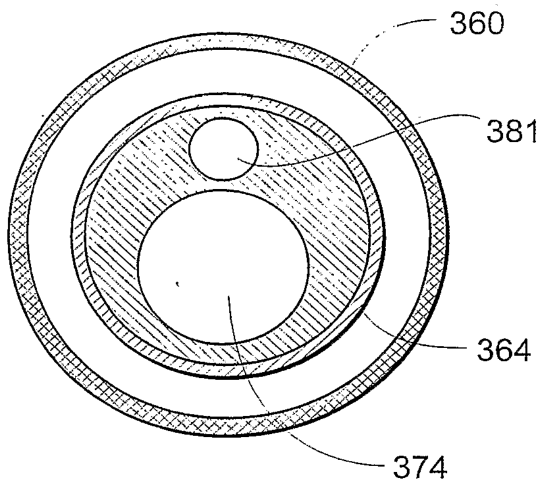


Fig. 47A

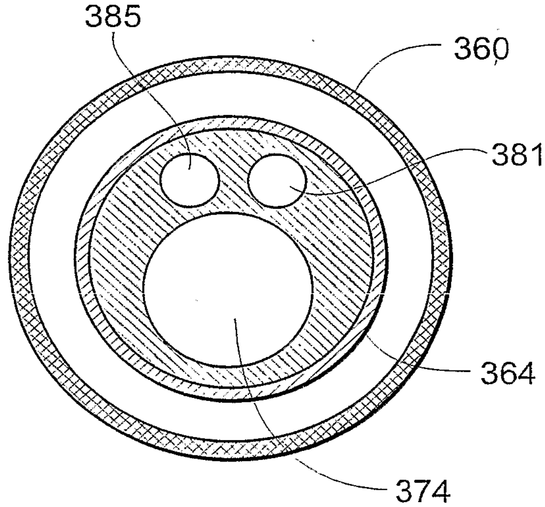


Fig. 47B

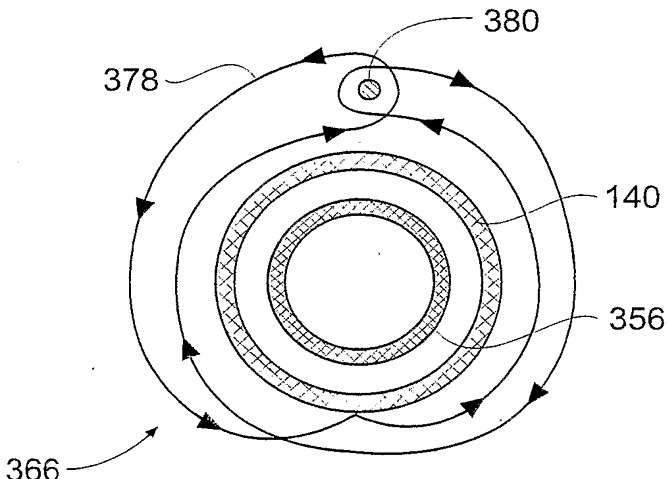
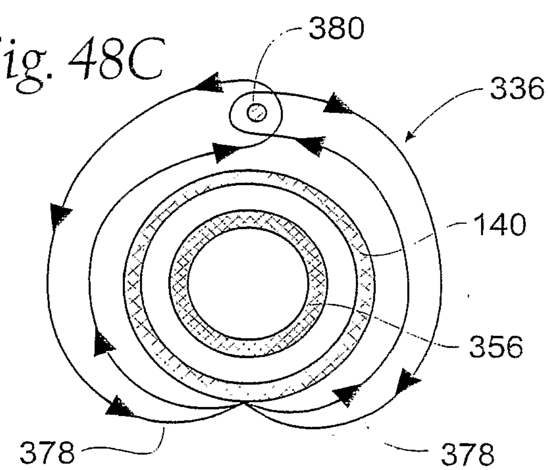


Fig. 48A

Fig. 48C



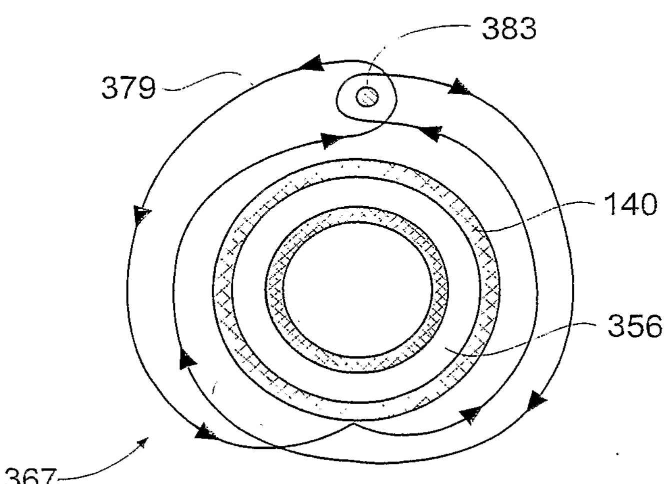


Fig. 48B

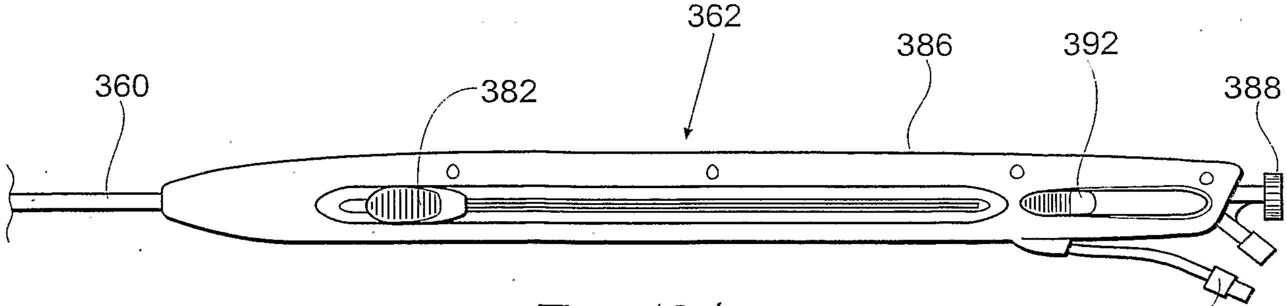


Fig. 49A

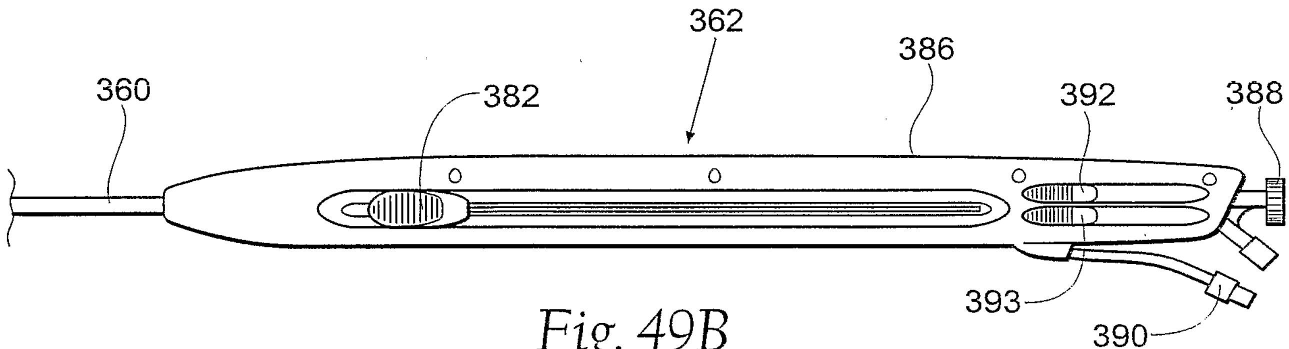


Fig. 49B

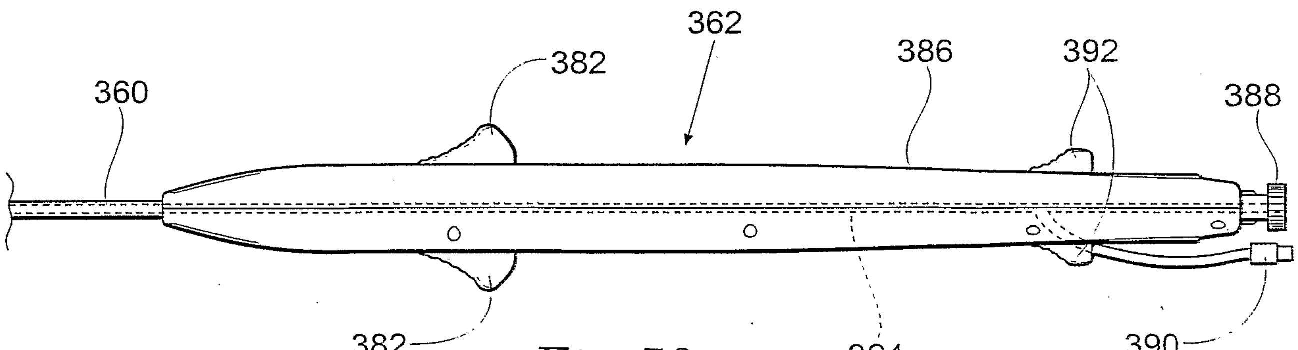
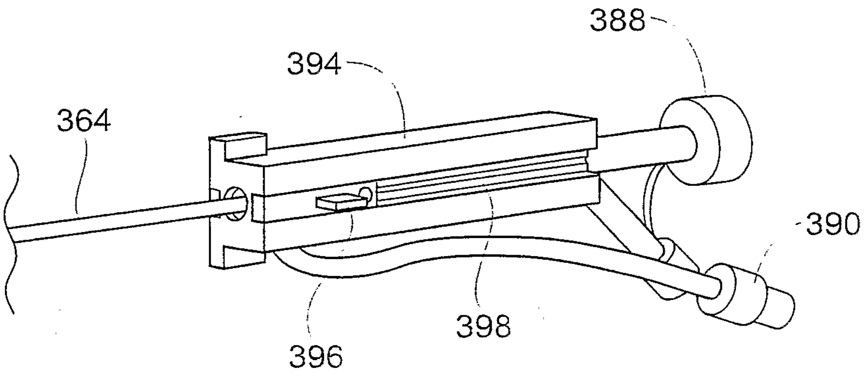


Fig. 50

Fig. 51



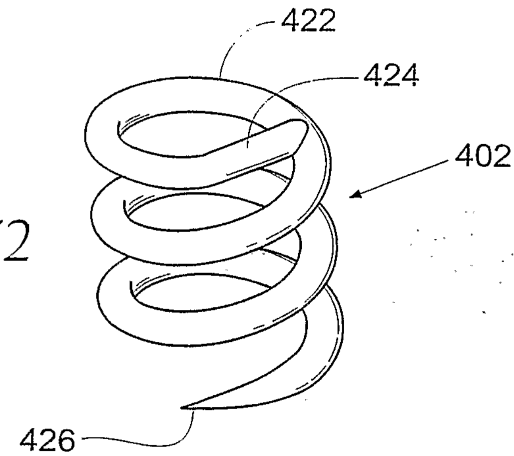


Fig. 52

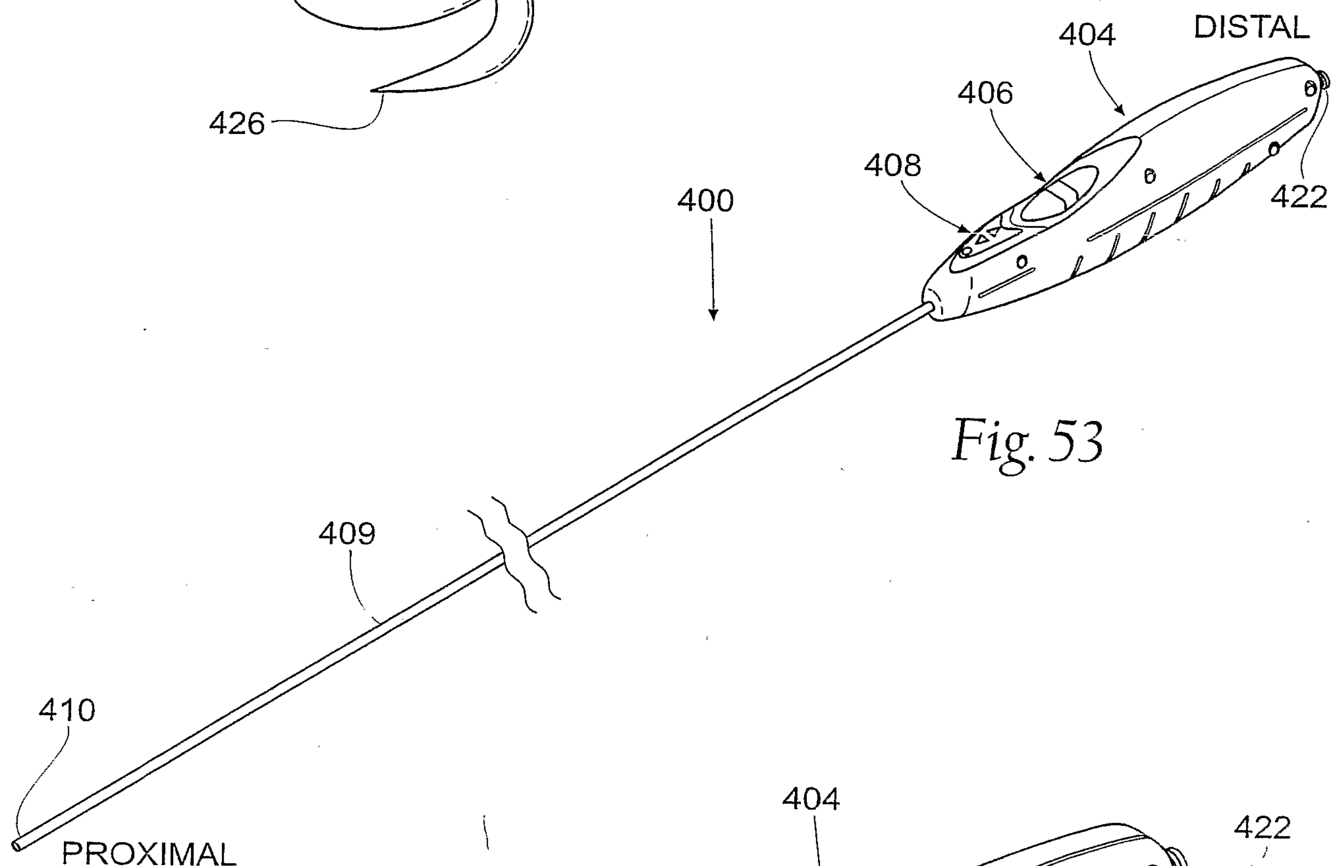


Fig. 53

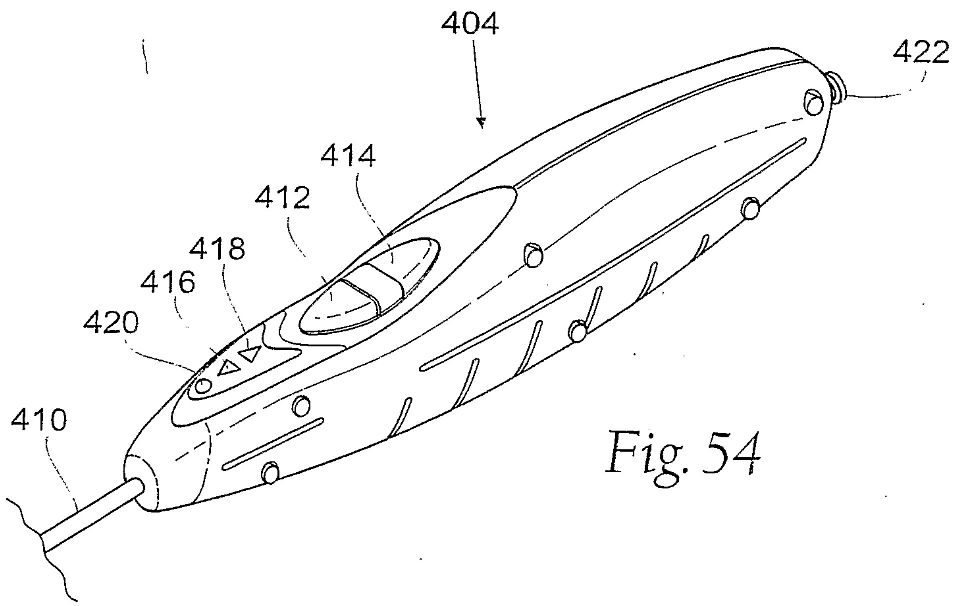


Fig. 54

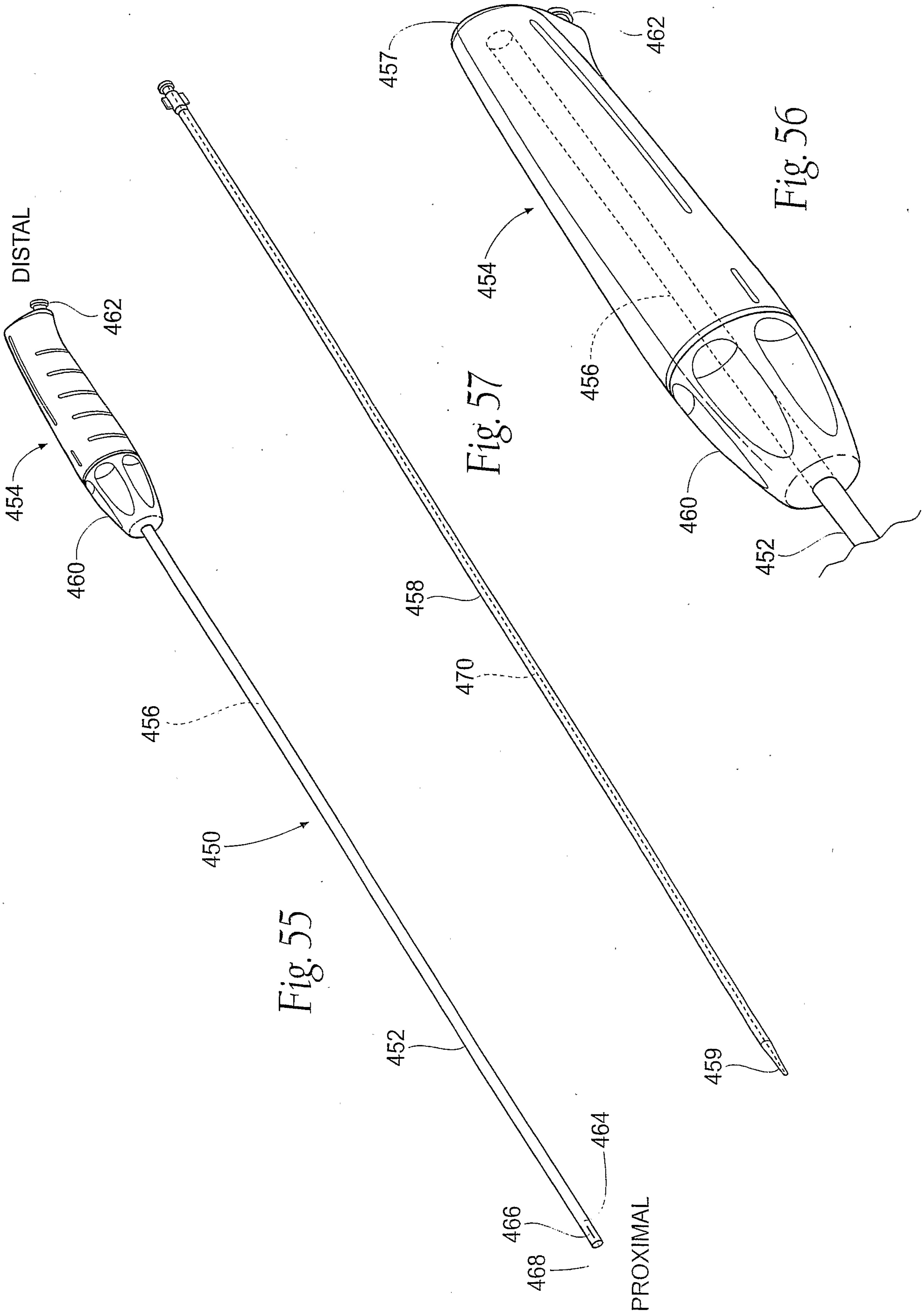


Fig. 55

Fig. 57

Fig. 56

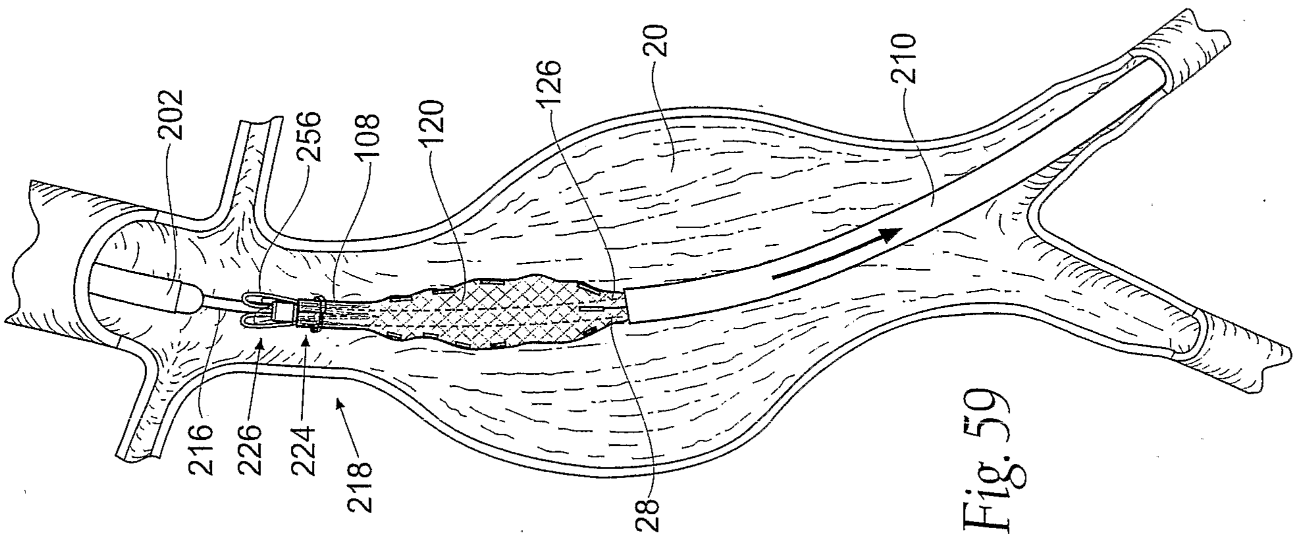

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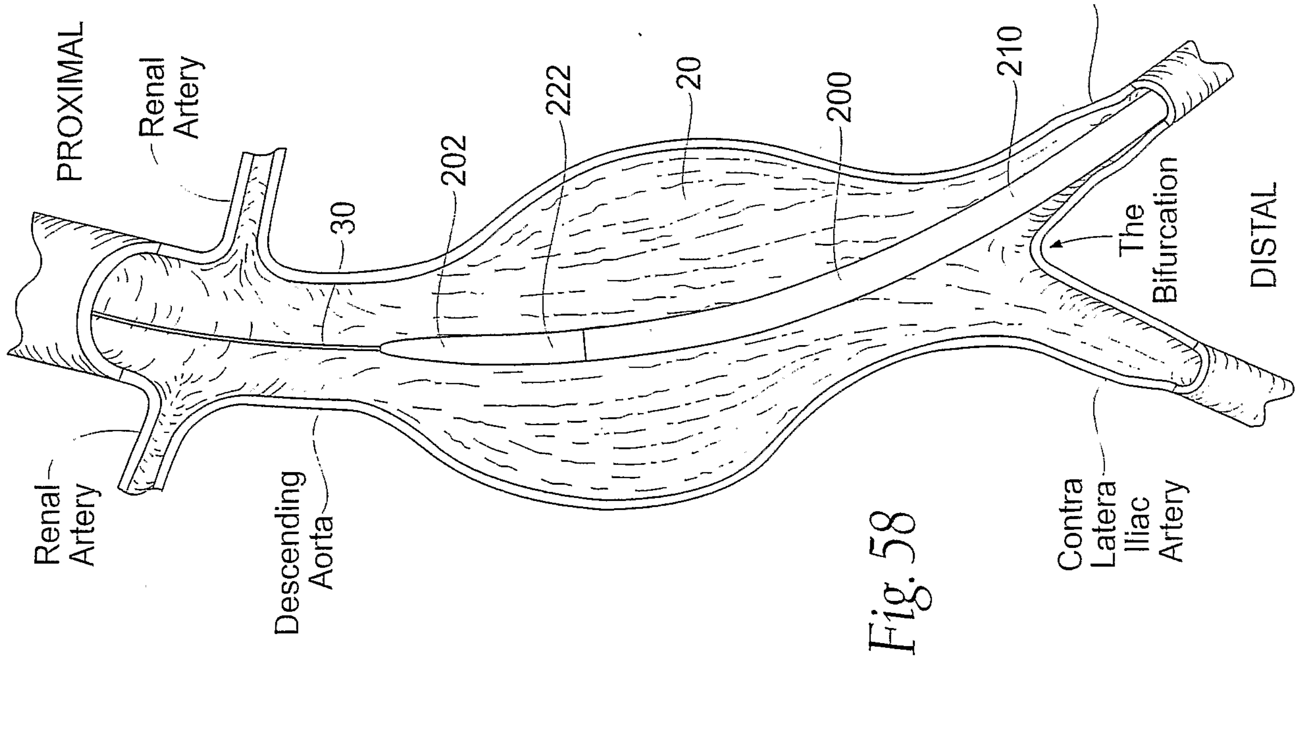
Fig. 59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210
Ipsi Lateral Iliac Artery
The Bifurcation
DISTAL
Renal Artery
Descending Aorta
Contra Latera Iliac Artery

Fig. 58

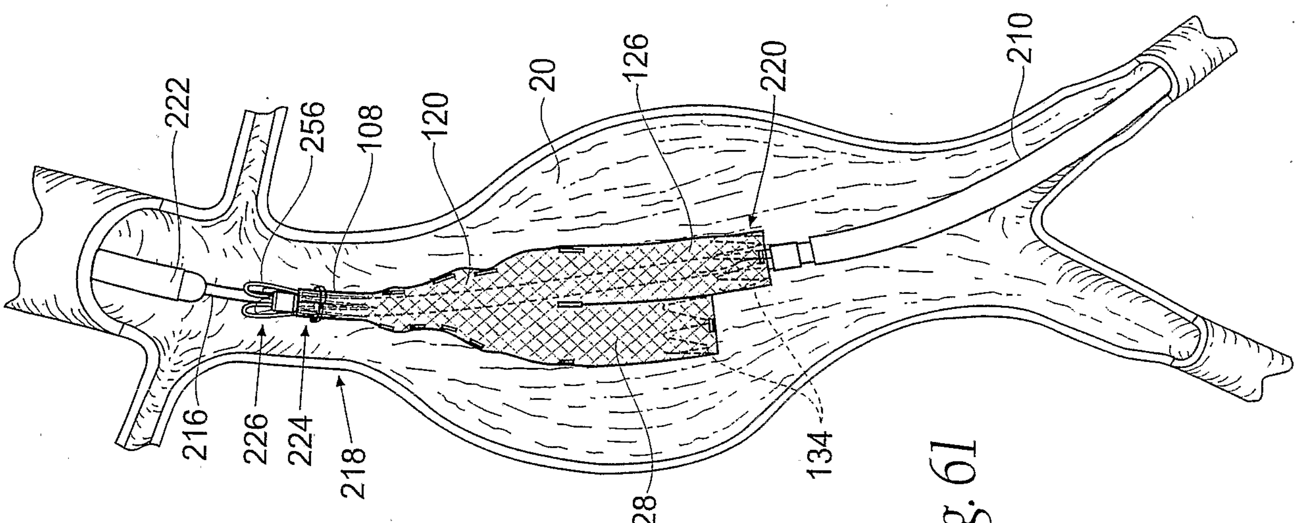
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Fig. 61

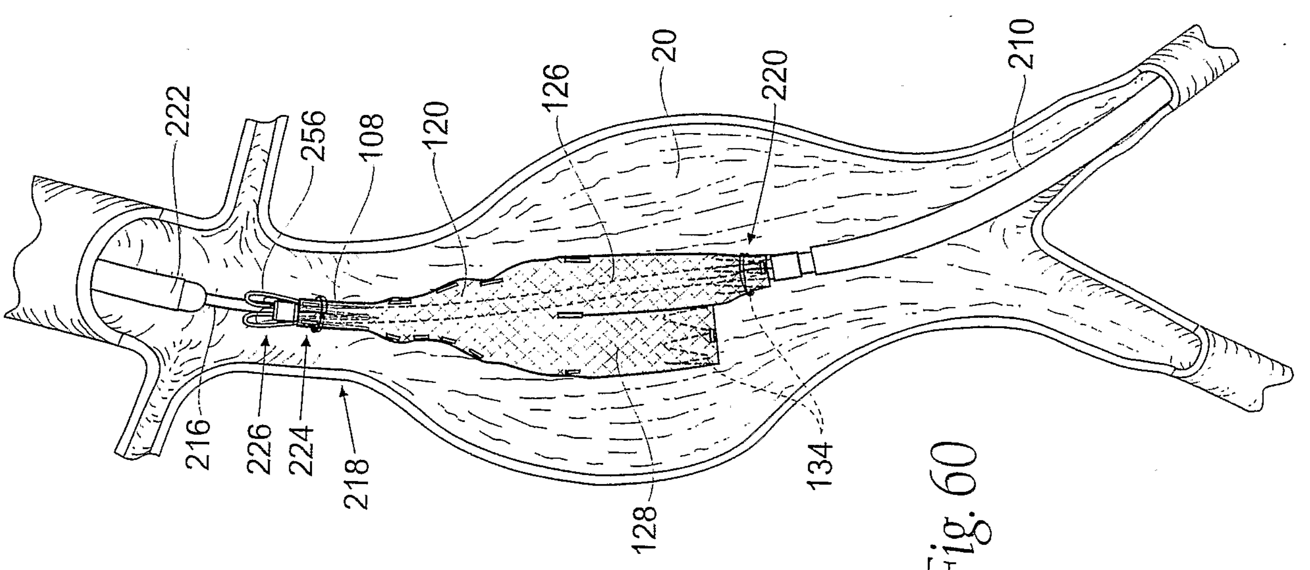
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Fig. 60

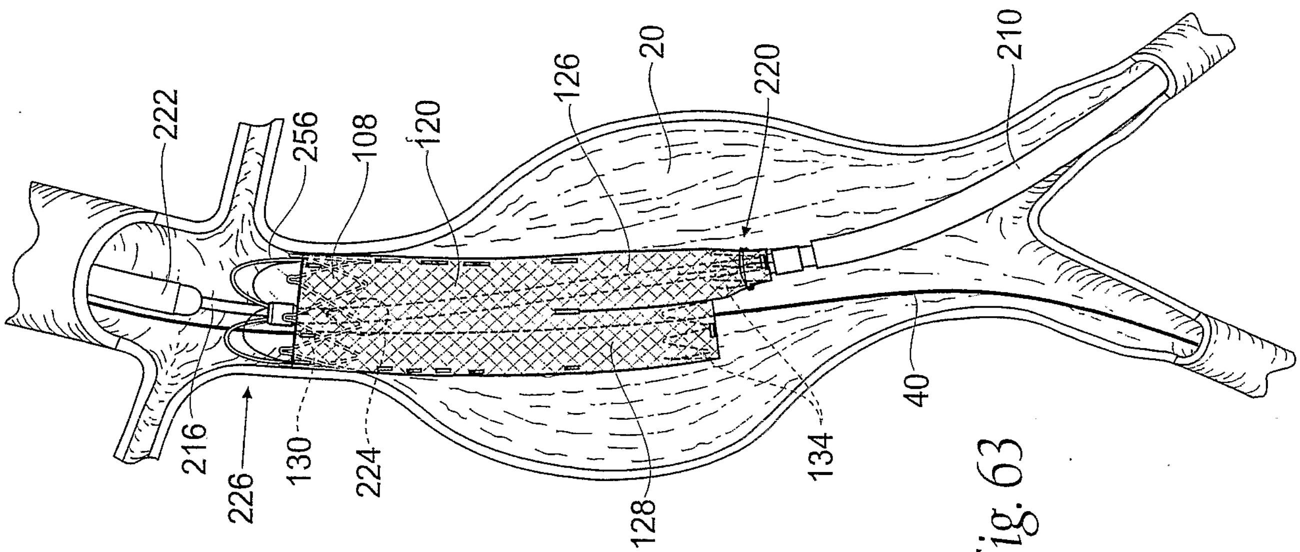
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Fig. 63

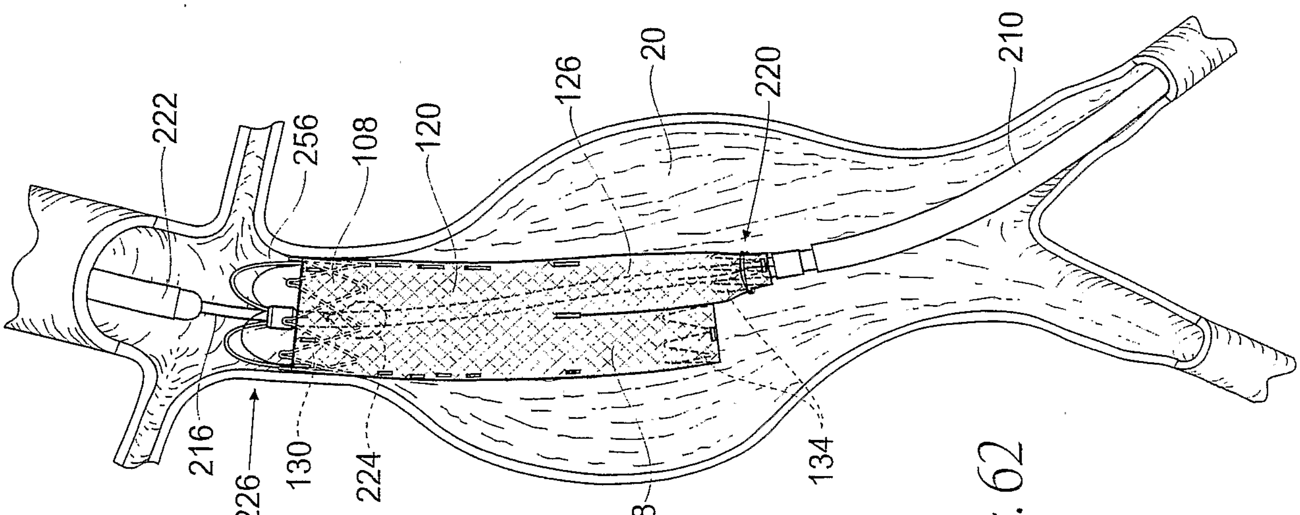
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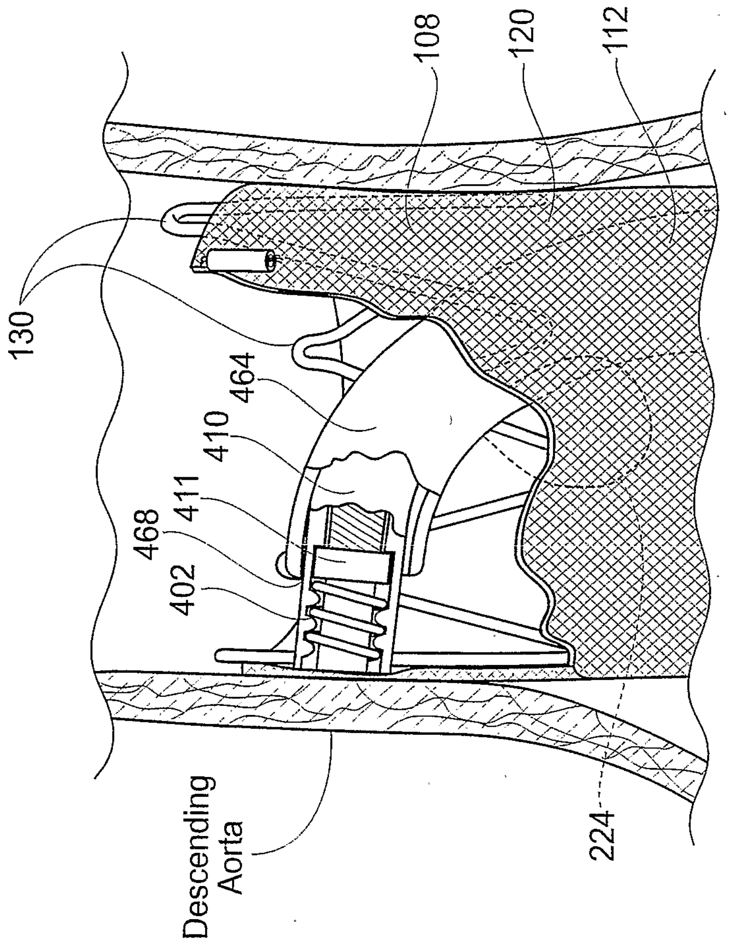
Fig. 62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Descending
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Fig. 65

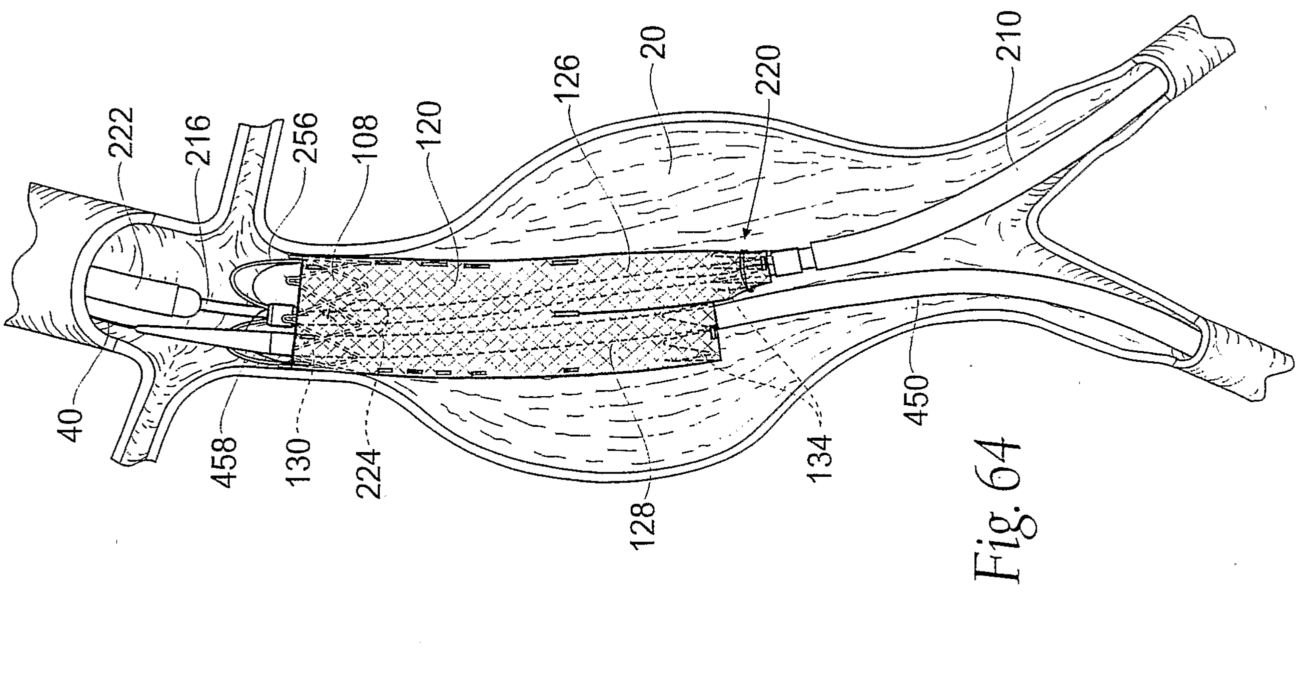
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Fig. 64

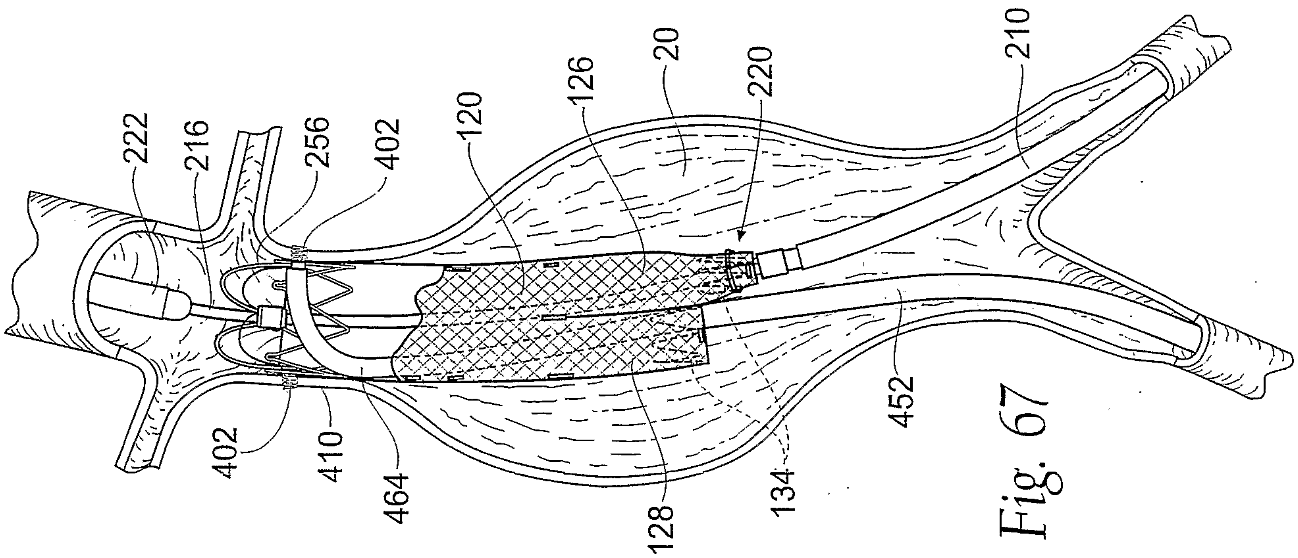
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Fig. 67

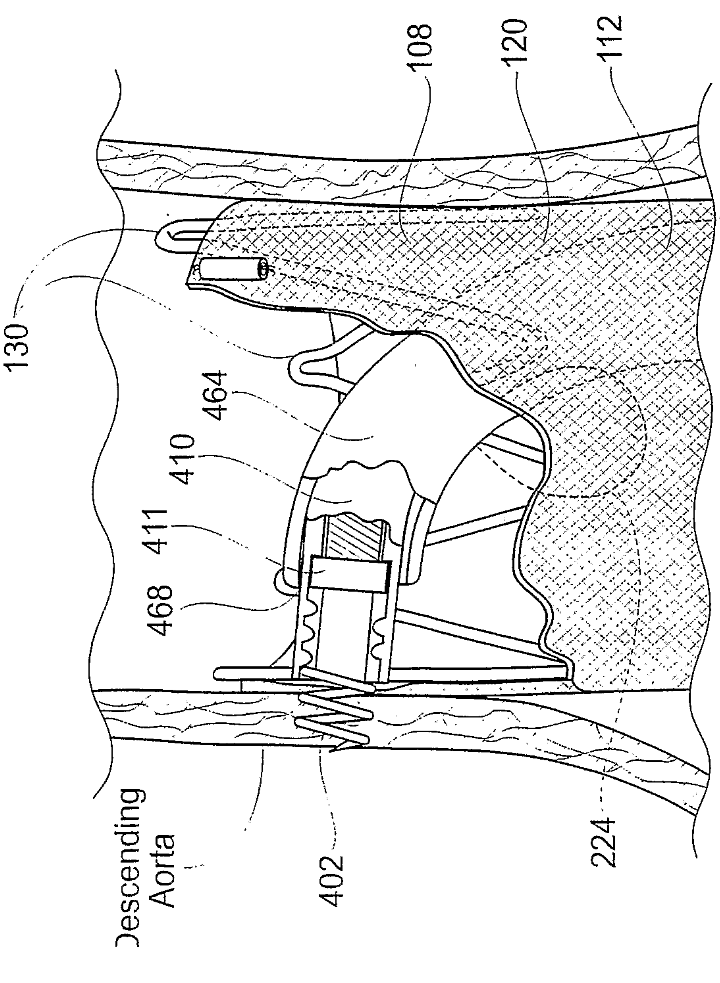
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Fig. 66

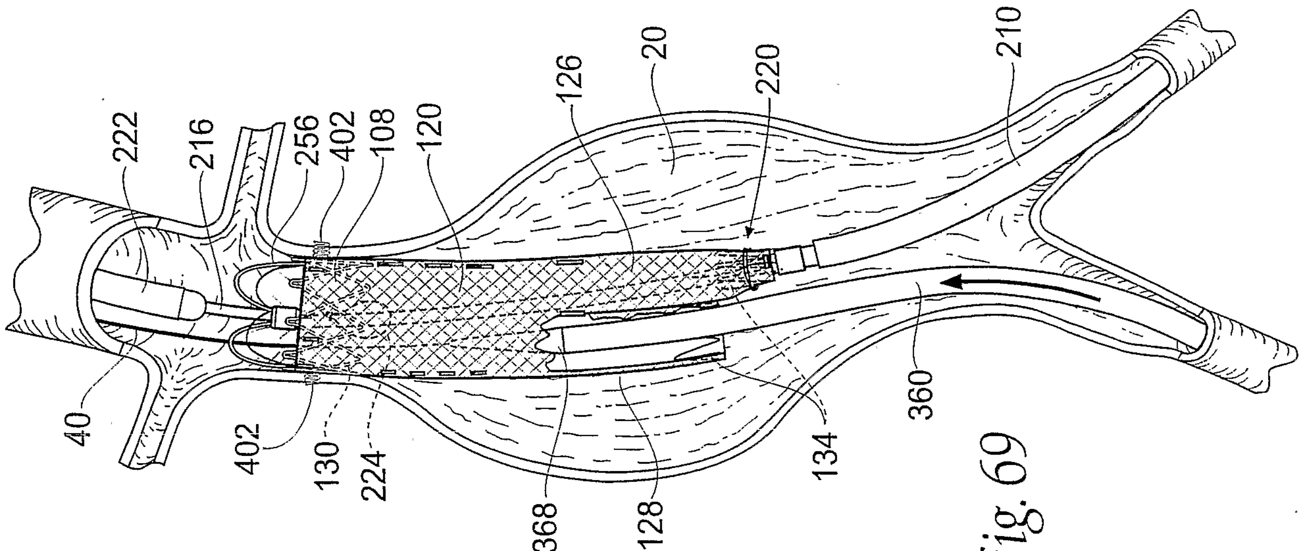
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Fig. 69

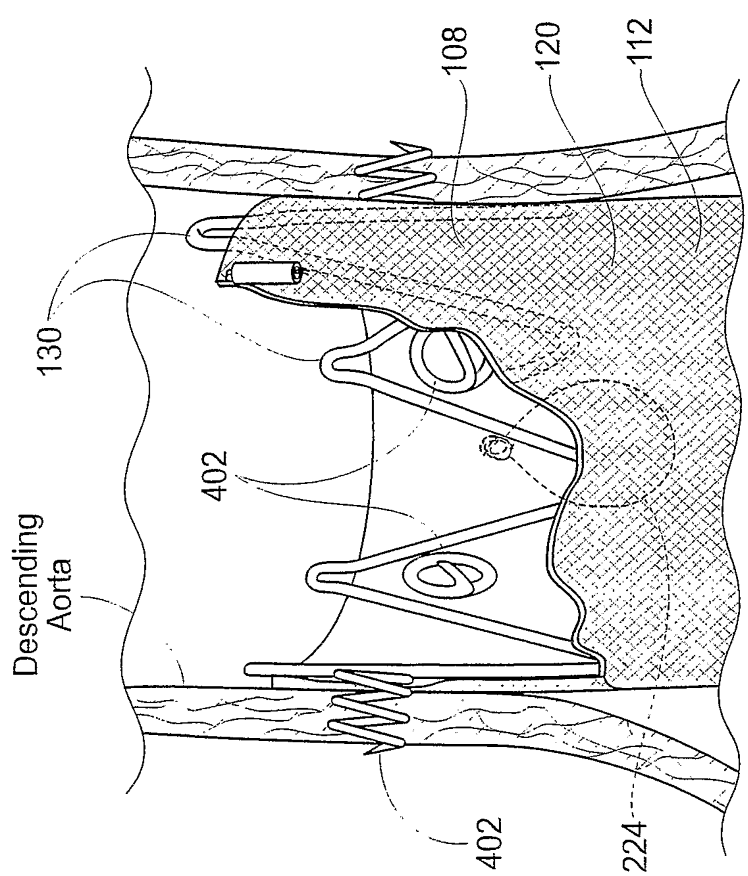
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Fig. 68

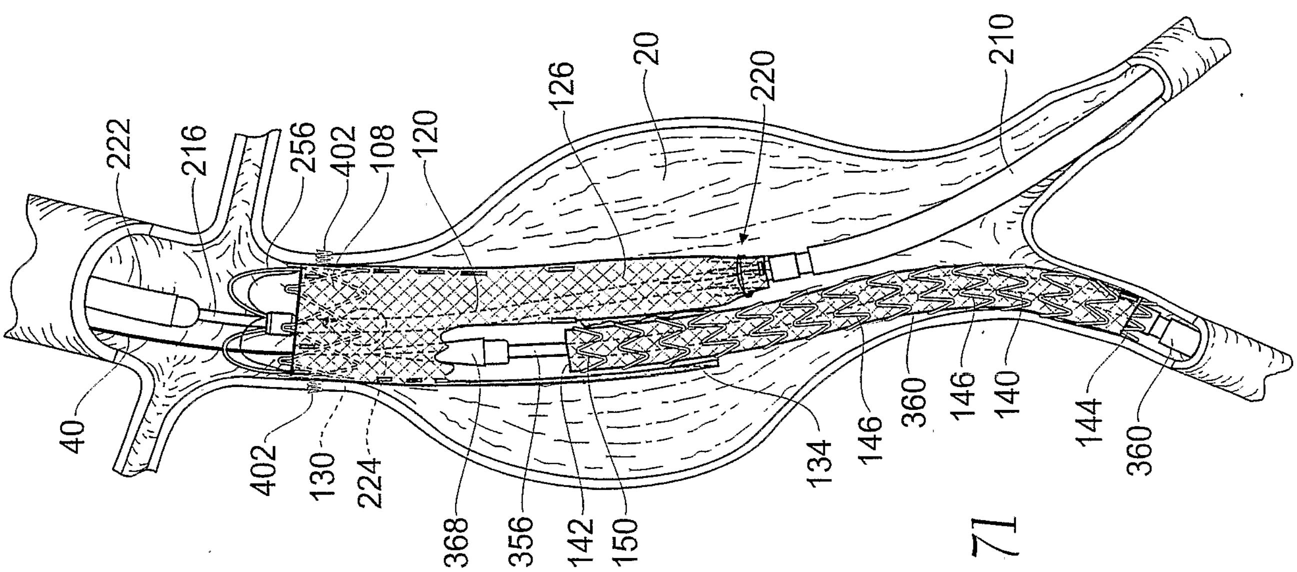
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Fig. 71

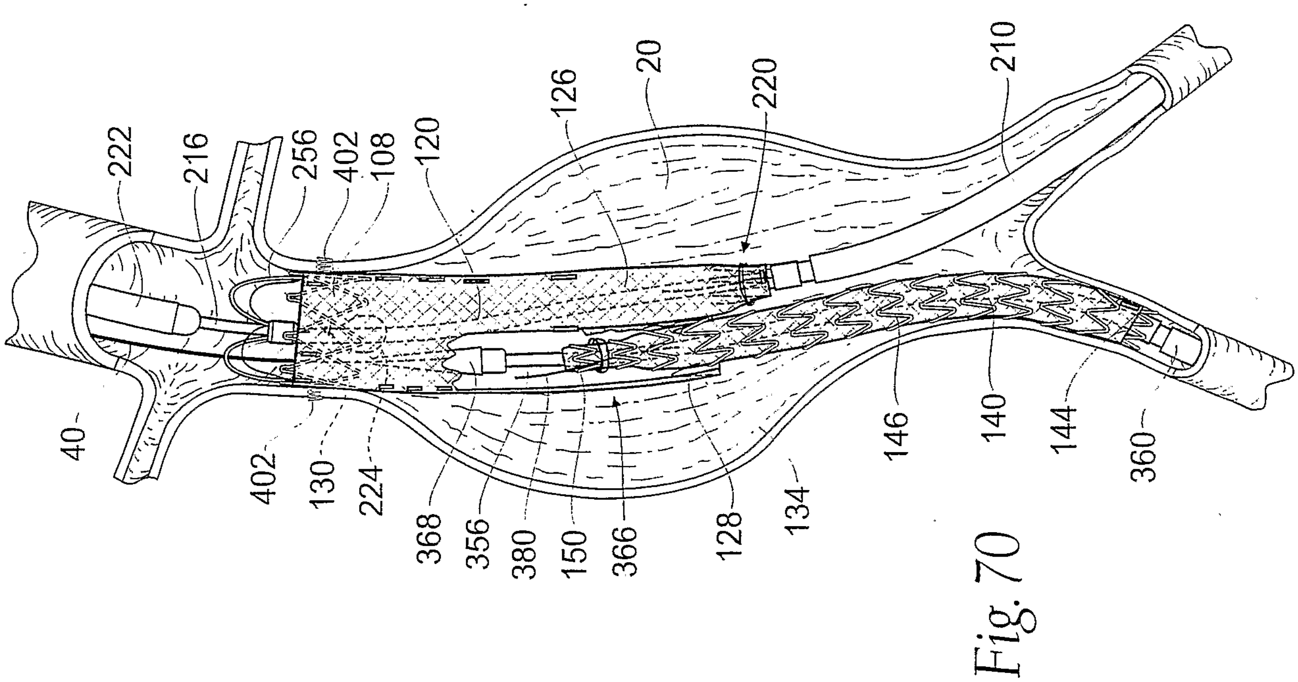
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Fig. 70

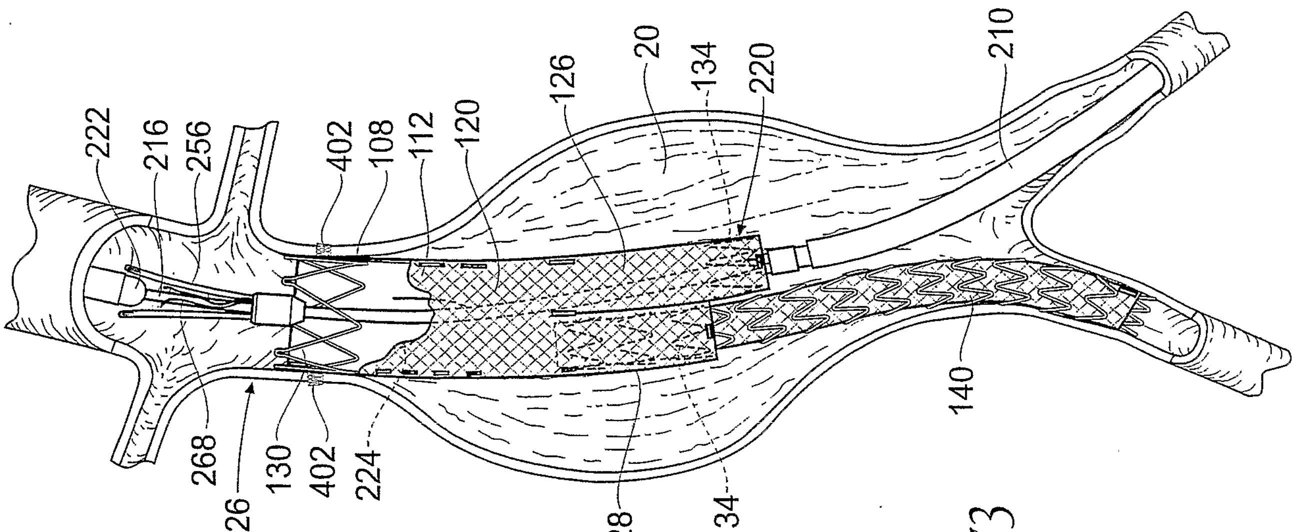
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Fig. 73

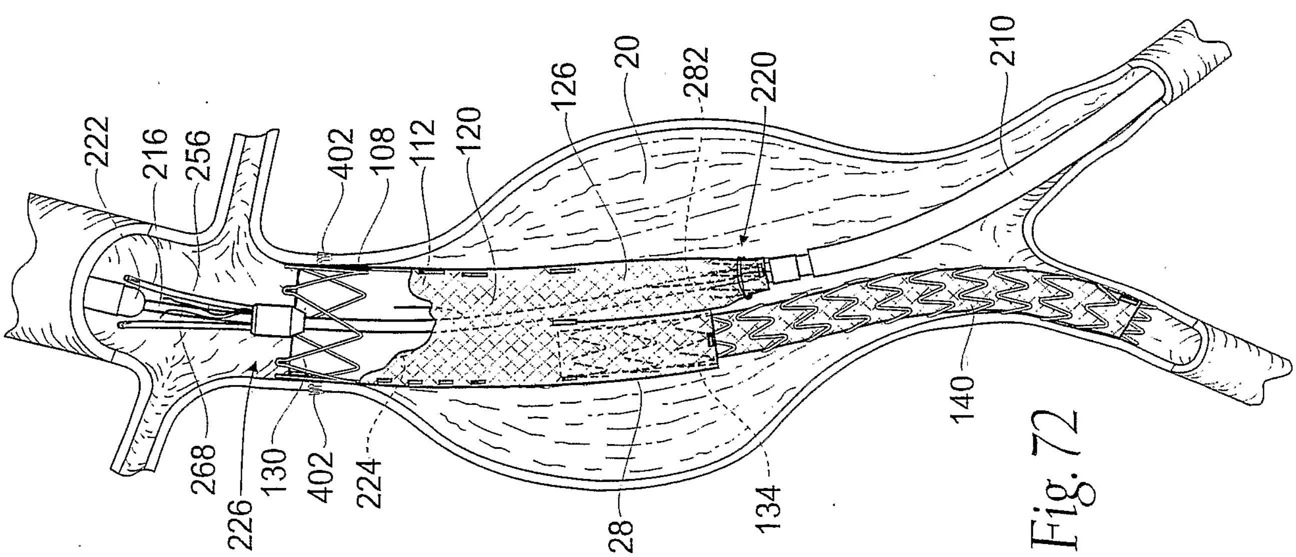
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Fig. 72

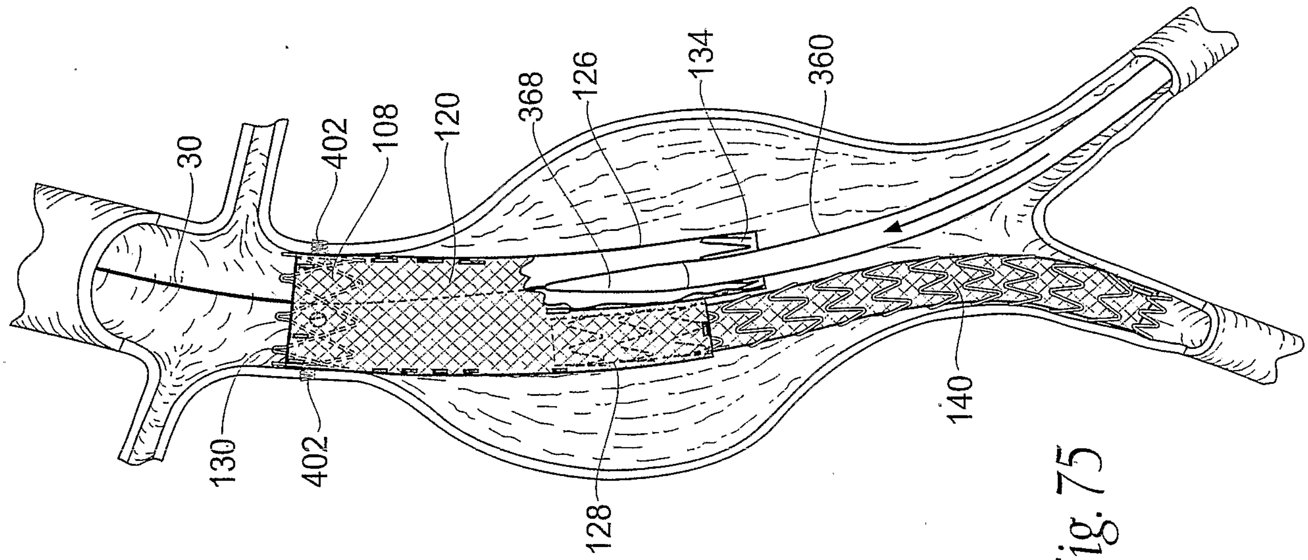
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Fig. 75

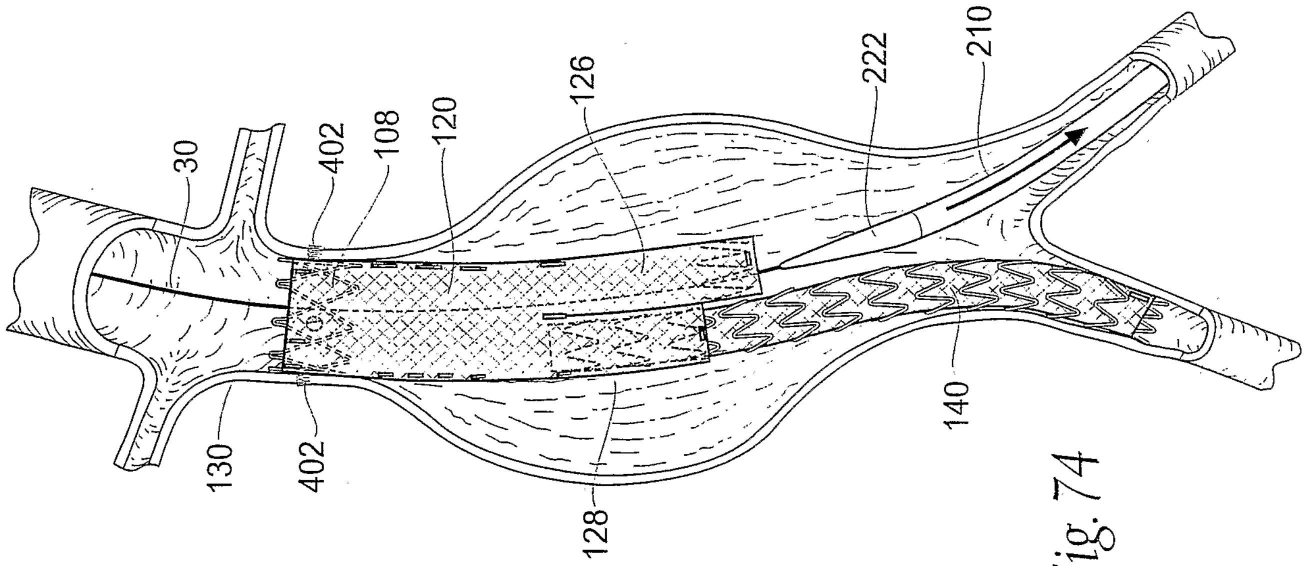
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Fig. 74

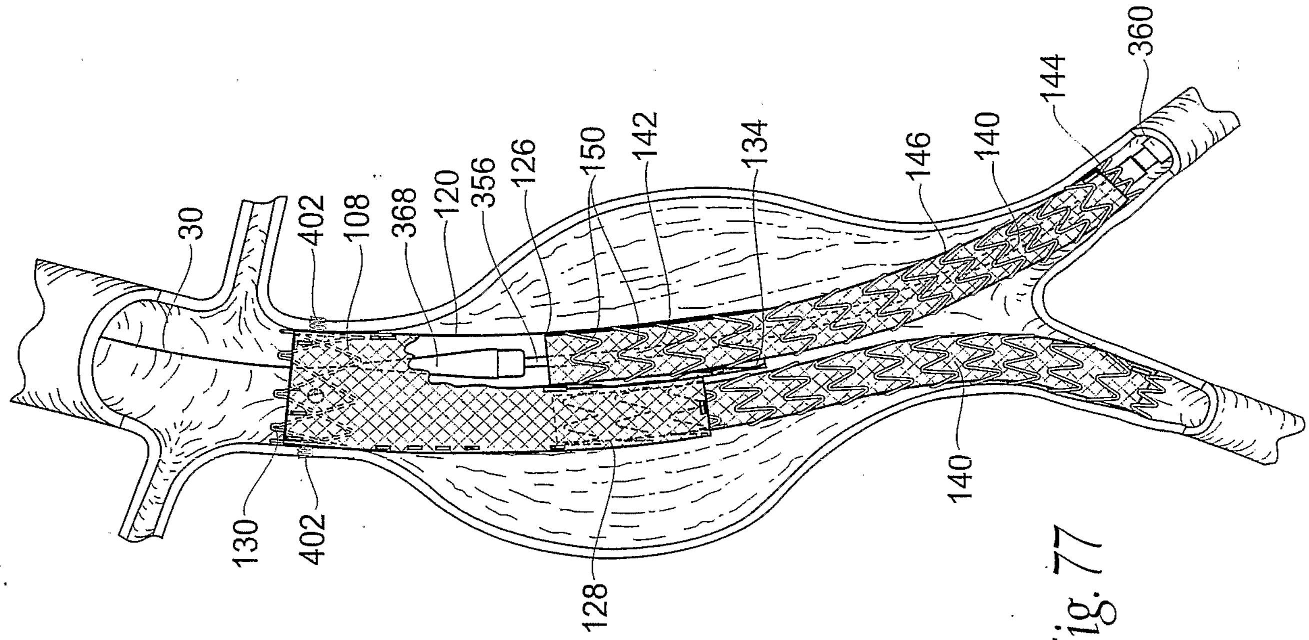
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Fig. 77

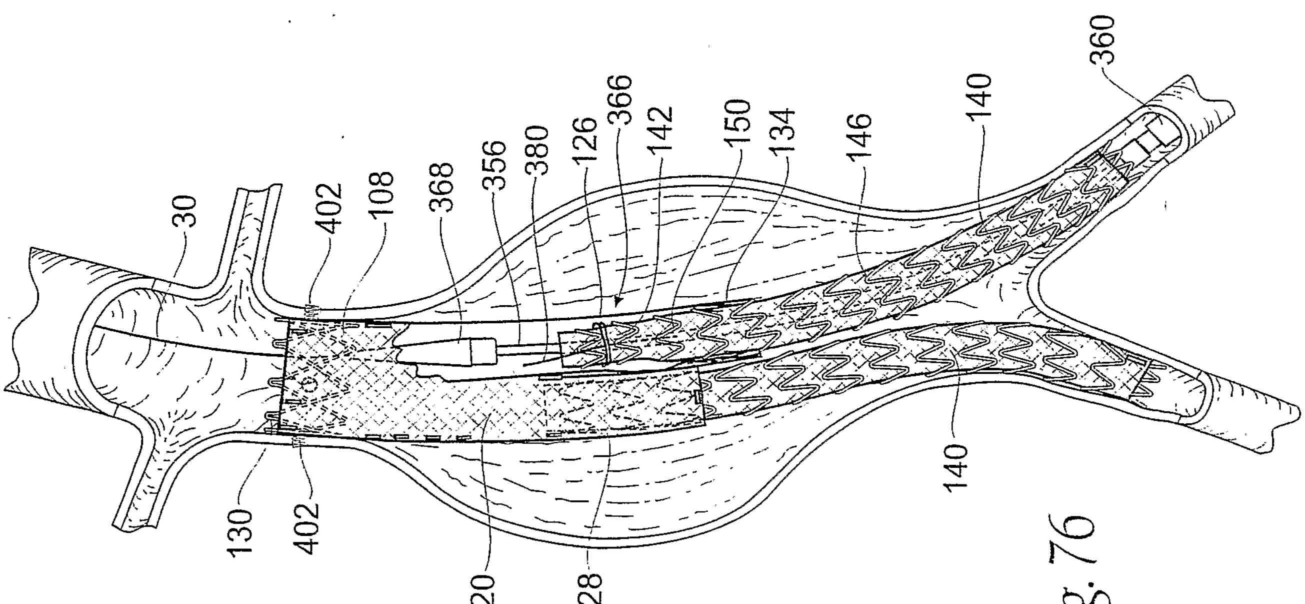
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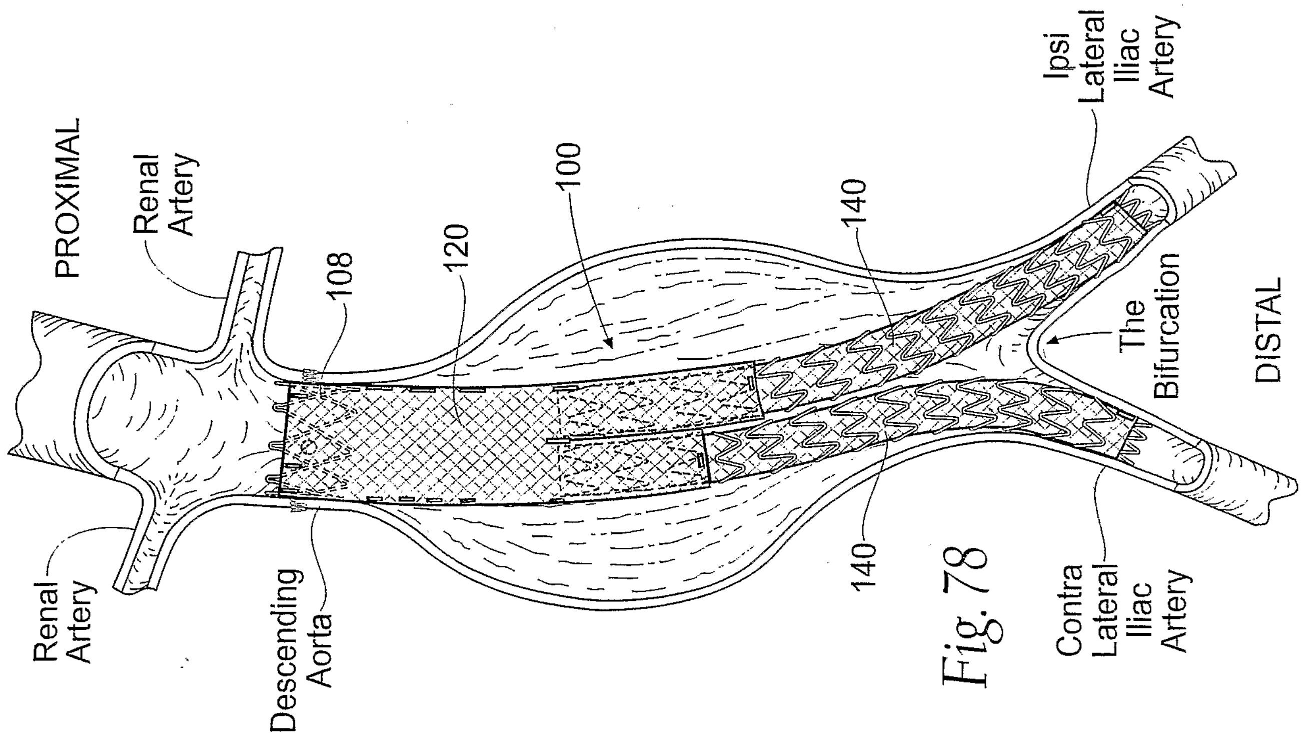
Fig. 76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The Bifurcation
DISTAL
Renal Artery
Descending Aorta
140
Contra Lateral Iliac Artery

Fig. 78

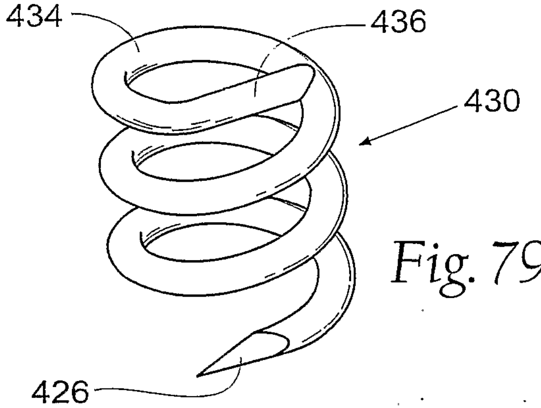

Fig. 79A

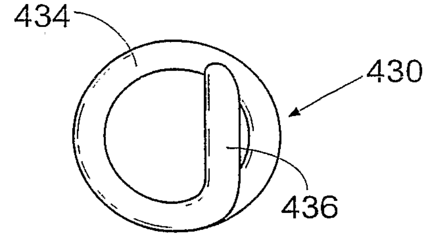

Fig. 79B

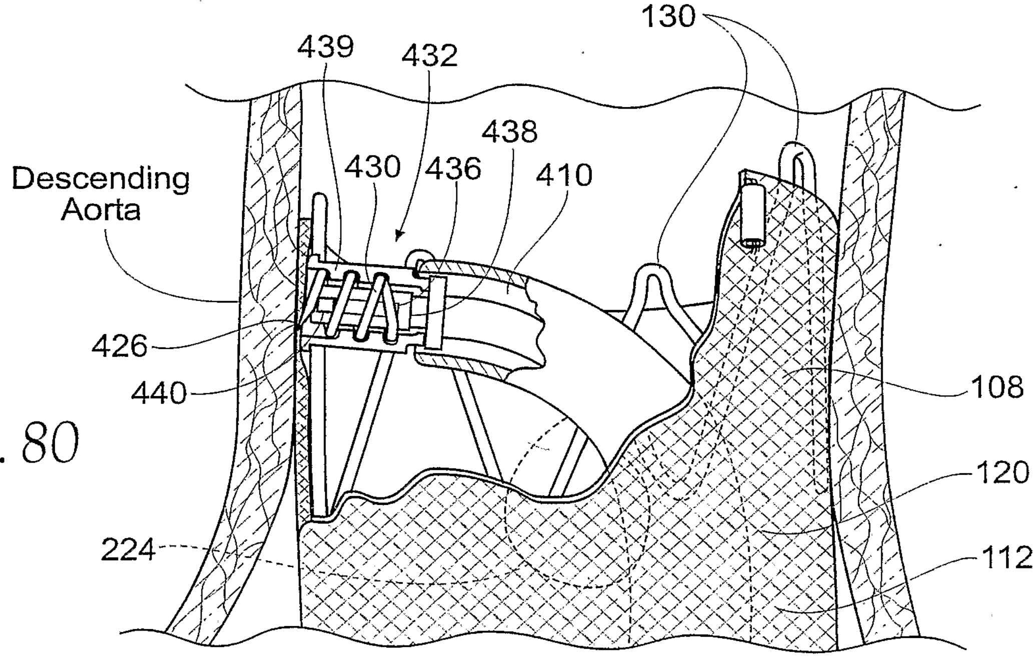

Fig. 80

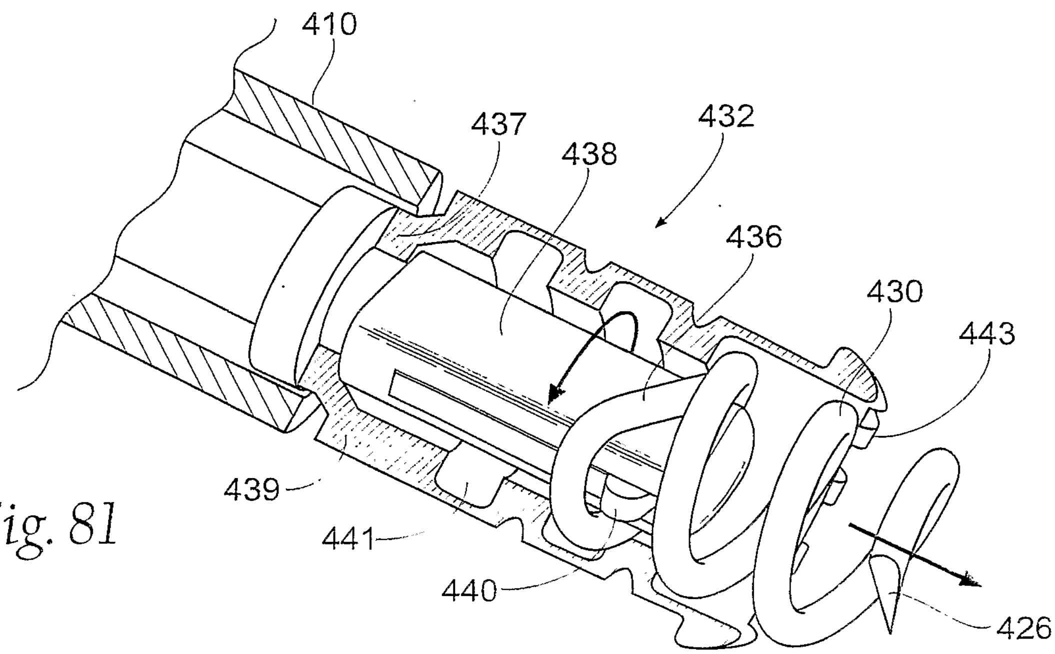

Fig. 81

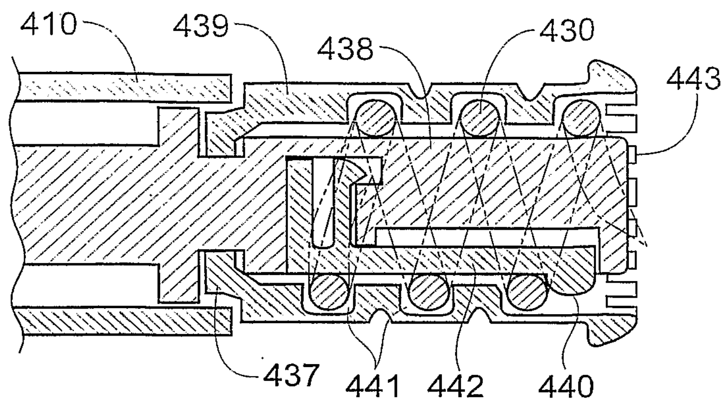

Fig. 82A

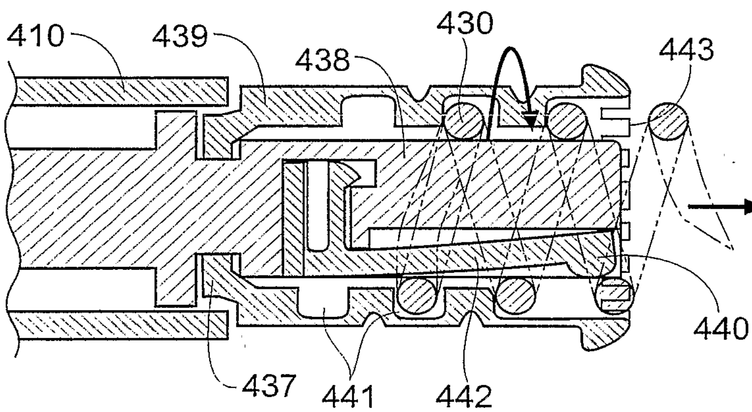

Fig. 82B

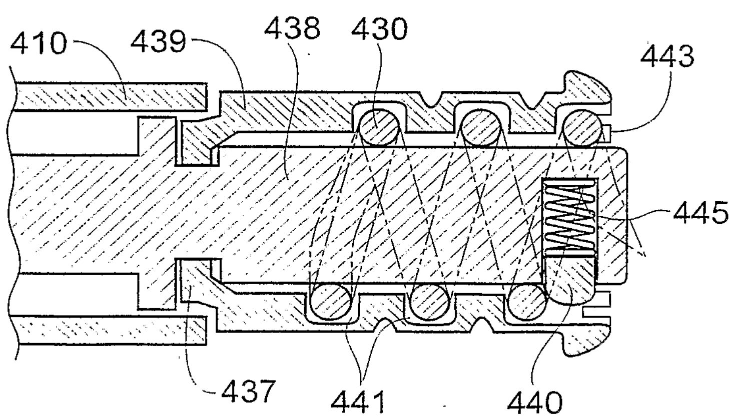

Fig. 82C

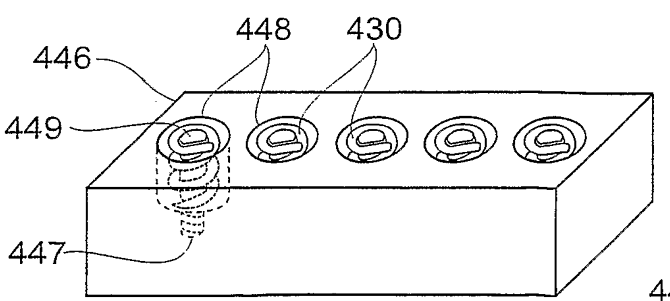

Fig. 83

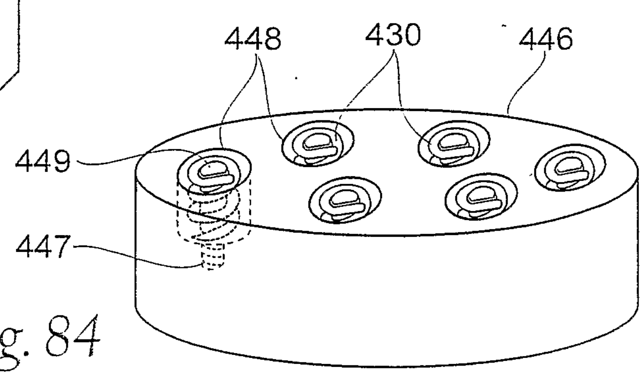

Fig. 84

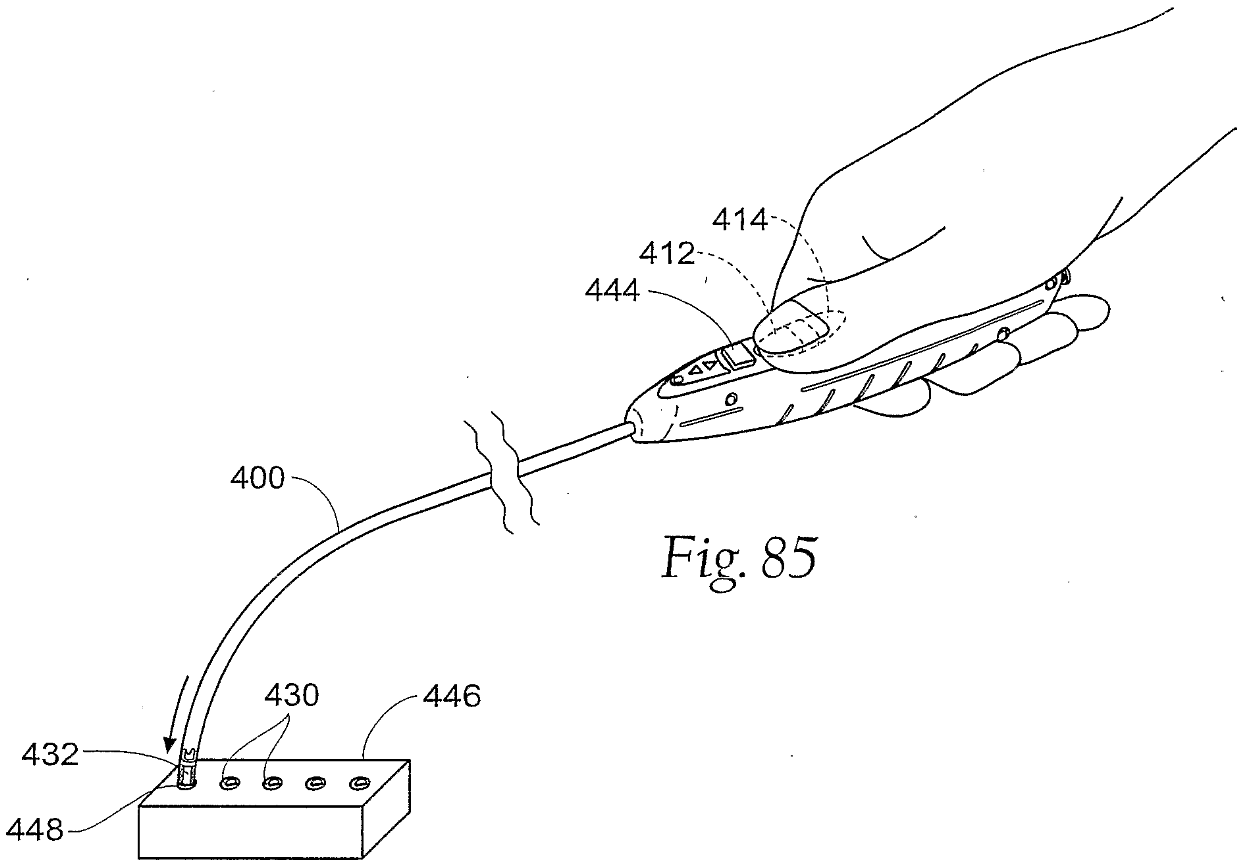
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Fig. 85

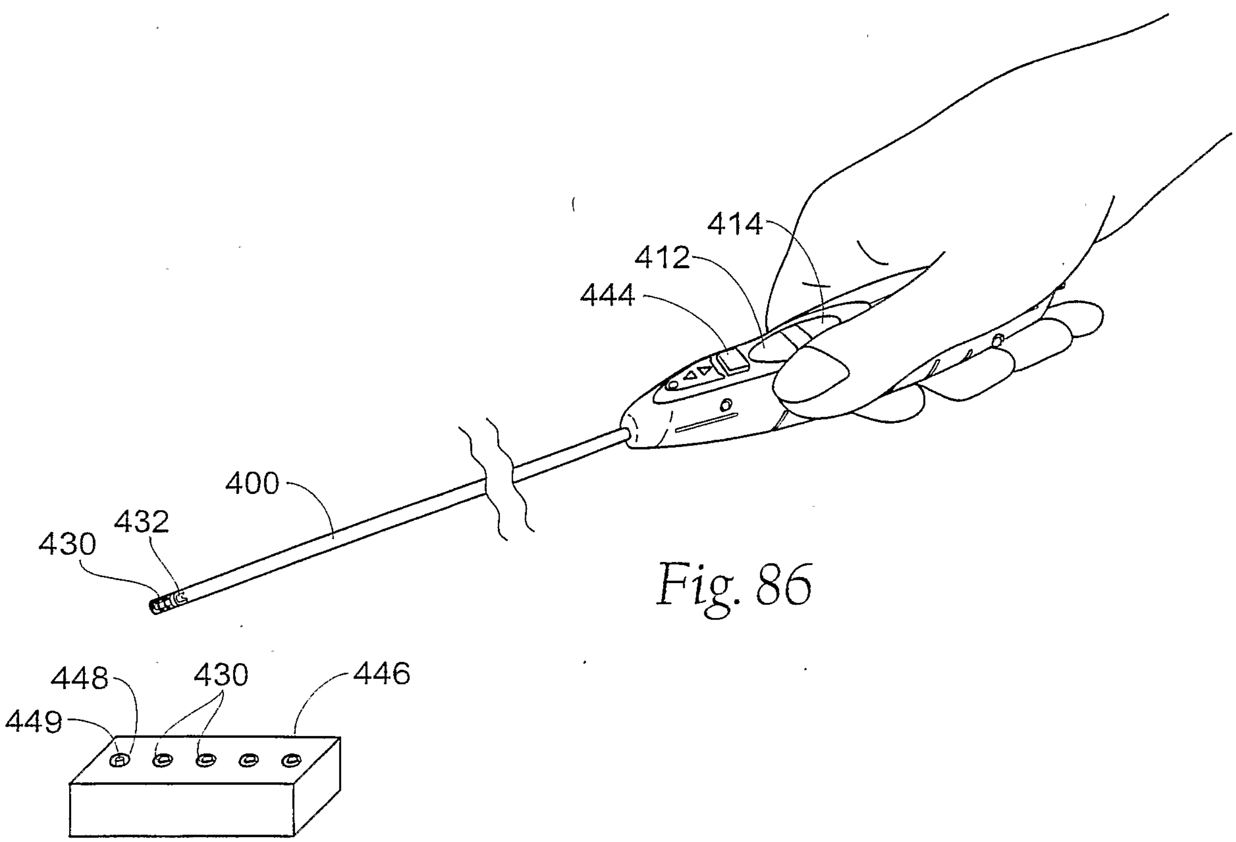
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Fig. 86

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(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BOLDUC, Lee** [US/US]; 716 Grape Avenue, Sunnyvale, CA 94087 (US). **LAROYA, Gilbert, S.** [US/US]; 4635 Armour Drive, Santa Clara, CA 95054 (US). **STAFFORD, Joshua** [US/US]; 1035 Windermere Avenue, Menlo Park, CA 94025 (US).

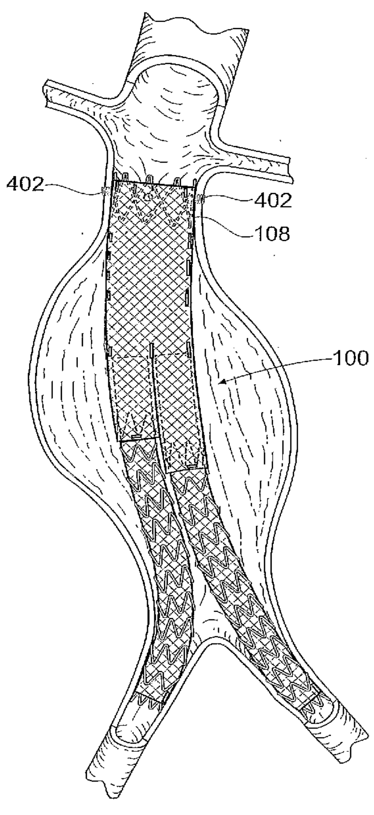
(74) Agents: **RYAN, Daniel, D.** et al.; Ryan, Kromholz, and Manion, S.C., P.O Box 26618, Brookfield, WI 53045 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,

[Continued on next page]

(54) Title: DEVICES, SYSTEMS, AND METHODS FOR PROSTHESIS DELIVERY AND IMPLANTATION



(57) Abstract: Devices, systems, and methods use a catheter device sized and configured for introduction to a targeted site in a hollow body organ or blood vessel. The catheter device includes a first release mechanisms coupled to the prosthesis to secure at least one region of the prosthesis to the catheter shaft, and a second release mechanism coupled to the prosthesis in cooperation with the first release mechanism to prevent full release of the at least one region of the at least one region of the prosthesis from the catheter shaft after actuation of the first release mechanism. A fastening device sized and configured- for introduction to the targeted site in the hollow body organ or blood vessel occupied by the catheter device, includes an actuator to deploy a fastener in the at least one region of the prosthesis after actuation of the first release mechanism and before actuation of the second release mechanism.

WO 2007/046955 A3

RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/33749

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IPC(8) - A61F 2/06 (2007.01)
USPC - 623/1.11
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 2/06 (2007.01)
USPC - 623/1.11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
USPTO EAST System (US, USPG-PUB, EPO, DERWENT), MicroPatent.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2004/0138734 A1 to (CHOBOTOV et al) 15 July 2004 (15.07.2004) entire document	8-12, 19-21 ------ 1-7, 13-18
Y	US 2004/0093057 A1 (BOLDUC et al) 13 May 2004 (13.05.2004) entire document	1-7, 13-18

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(54) **Title:** ENDOVASCULAR ANEURYSM DEVICES, SYSTEMS, AND METHODS

(57) **Abstract:** Devices, systems, and methods for implanting prostheses in the body lumens rely on tacking or anchoring the prostheses with separately introduced fasteners. After initial placement, a fastener applier system is introduced within the expanded prostheses to deploy a plurality of fasteners to at least- one prosthesis" end. The fasteners are usually helical fasteners which are releasably restrained on the fastener driver, and are delivered by rotation of the fastener driver. The fasteners may be applied singly, typically in circumf erentially spaced-apart patterns about the interior of at least one end of the prosthesis. A lumen extension or lumens may be coupled to the prosthesis to extend the reach of the prosthesis within the implantation site. Fasteners may also be applied to the lumen extensions .

ENDOVASCULAR ANEURYSM DEVICES, SYSTEMS, AND METHODS

Related Applications

This application is a continuation-in-part of co-pending United Stated Patent Application Serial No. 11/255,116, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which is incorporated herein by reference. This application also is a continuation-in-part of co-pending United Stated Patent Application Serial No. 10/692,283, filed October 23, 2003, and entitled "Prosthesis Delivery Systems and Methods," which claims the benefit of United States Provisional Patent Application Serial No. 60/488,753, filed July 21, 2003, and entitled "Endoprosthesis Delivery Systems and Methods." This application also is a continuation-in-part of co-pending United Stated Patent Application Serial No. 10/786,465, filed February 25 2004, and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ." This application is also a continuation-in-part of co-pending United States Patent Application 11/693,255, filed June 24, 2005, entitled "Multi-Lumen Prosthesis Systems and Methods," which is a division of United States Patent Application Serial No. 10/693,255, filed 24 October 2003 (now United States Patent 6,929,661), which claims the benefit of United

States Provisional Patent Application Serial No. 60/489,011, filed July 21, 2003, and entitled "Bifurcated Prosthesis Systems and Methods." This application also is a continuation-in-part of co-pending United Stated Patent Application Serial No. 10/307,226, filed 29 November 2002, and entitled "Intraluminal Prosthesis Attachment Systems and Methods." This application is also a continuation-in-part of copending United States Patent Application Serial Number 10/669,881, entitled "Catheter-Based Fastener Implantation Apparatus and Methods with Implantation Force Resolution." This application is also a continuation-in-part of copending United States Patent Application Serial No. 11/166,411, filed June 24, 2005, entitled "Endovascular Aneurysm Repair System," which is a division of United Stated Patent Application Serial No. 10/271,334, filed 15 October 2002 (now United States Patent No. 6,960,217), which claims the benefit of United States Provisional Patent Application Serial No. 60/333,937, filed 28 November 2001, and entitled "Endovascular Aneurysm Repair System." Each of the preceding applications is incorporated herein by reference.

Field of the Invention

The invention relates generally to devices, systems, and methods for the delivery and implantation of a prosthesis to a targeted site within the body, e.g., for the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel.

Background of the Invention

The weakening of a vessel wall from damage or disease can lead to vessel dilatation and the formation of an aneurysm. Left untreated, an aneurysm can grow in size and may eventually rupture.

For example, aneurysms of the aorta primarily occur in the abdominal region, usually in the infrarenal area

between the renal arteries and the aortic bifurcation. Aneurysms can also occur in the thoracic region between the aortic arch and renal arteries. The rupture of an aortic aneurysm results in massive hemorrhaging and has a high rate of mortality.

Open surgical replacement of a diseased or damaged section of vessel can eliminate the risk of vessel rupture. In this procedure, the diseased or damaged section of vessel is removed and a prosthesis, made either in a straight or bifurcated configuration, is installed and then permanently attached and sealed to the ends of the native vessel by suture. The prosthesis for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The prosthesis are longitudinally unsupported so they can accommodate changes in the morphology of the aneurysm and native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co-morbidities.

Endovascular aneurysm repair has been introduced to overcome the problems associated with open surgical repair. The aneurysm is bridged with a vascular prosthesis, which is placed intraluminally. Typically these prostheses for aortic aneurysms are delivered collapsed on a catheter through the femoral artery. These prostheses are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel. Unlike open surgical aneurysm repair, intraluminally deployed prostheses are not sutured to the native vessel, but rely on either barbs extending from the stent, which penetrate into the native vessel during deployment, or the radial expansion force

of the stent itself is utilized to hold the prosthesis in position. These prosthesis attachment means do not provide the same level of attachment when compared to suture and can damage the native vessel upon deployment.

Accordingly, there is a need for improved prosthesis delivery devices, systems, and methods that deliver a prosthetic graft to a body lumen, the prosthesis being able to adapt to changes in aneurysm morphology and able to be deployed safely and without damage to the native vessel.

Summary of the Invention

One aspect of the invention provides a system comprising a guide defining an access path into a vessel or hollow body organ and a fastener applier comprising a catheter sized and configured for introduction along the access path to a site targeted for implantation of at least one fastener. The guide includes a distal region with terminus. The fastener applier includes an actuated member that is selectively operable to generate an implantation force to implant the at least one fastener within tissue at the site. According to this aspect of the invention, the catheter includes indicia visible to a naked eye to mark when the actuated member rests at a desired distance along the access path short of the terminus of the distal region and is therefore still out of contact with tissue. The visible indicia makes it possible for the physician, without resort to fluoroscopic visualization or other visualizations techniques that augment human sight, to always know whether the fastener is within or outside the guide.

This aspect of the invention also provides instructions for using the guide and fastener applier in which, as the actuated member is being introduced along the access path toward the terminus, the operator or physician is instructed to view the indicia with a naked

eye, to detect when the actuated member rests at a desired distance along the access path short of the terminus of the distal region.

Another aspect of the invention provides for a fastener applier an electrically powered drive member coupled to the driven member and a controller coupled to the drive motor. According to this aspect of the invention, the controller includes a LOAD state. In the LOAD state, the controller operates in response to an input command for delivering electrical current to the drive member to drive the driven member in a first direction to load a fastener onto the driven member. The controller senses electrical current delivered to the drive member while loading the fastener onto the driven member. The controller terminates delivery of electrical current to the driven member when a prescribed amount of current is delivered to the drive member, thereby terminating the LOAD state.

On one embodiment, the controller also includes an UNWIND state that follows the LOAD state. In the UNWIND state, which is operative after termination of the LOAD state, the controller delivers electrical current to the drive member to drive the driven member in a second direction. The controller senses a period of operation of the driven member in the second direction which is sufficient to reduce torque windup on the driven member created during the LOAD state. The controller terminates delivery of electrical current to the driven member after the period of operation, thereby terminating the UNWIND state. According to this aspect of the invention, the fastener applier enters a READY TO APPLY state with a minimum of torque windup associated with the driven element.

Another aspect of the invention provides a fluid seal assembly usable in association with, e.g., a

catheter assembly including an operative element that, in use, is exposed to a body fluid, a control element, a control filament coupled at one end to the control element and to an opposite end to the operative element. In this arrangement, the seal assembly is positioned between the control element and the operative element, and the control filament passes through the seal assembly to prevent contact between the body fluid and the control element.

According to this aspect of the invention, the seal assembly comprises a first seal component with at least one guide tube formed therein, and a second seal component with at least one guide tube formed therein. The second seal component registers with the first seal component with at least one guide tube in the second component coaxially aligned with at least one guide tube in the first component. A septum is sandwiched between the first and second seal components. The septum accommodates passage of the control filament from one the coaxially aligned guide tubes, through the septum, to the other one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament that prevents the control element from contacting body fluid to which the operative element is exposed during use.

Other features and advantages of the invention shall be apparent based upon the accompanying description, drawings, and claims.

Brief Description of the Drawings

Fig. 1 is a view of the components of a system for repairing an endovascular aneurysm.

Fig. 2 is a view of the components of the system shown in Fig. 1 consolidated for use in a multiple piece kit, along with instructions for their use.

Fig. 3A is a view of the main body of the endovascular graft that forms a part of the system shown

in Fig. 1.

Fig. 3B is a view of a lumen extension of the endovascular graft that forms a part of the system shown in Fig. 1.

Fig. 3C is an anatomic view of the main body and lumen extensions of the graft assembly assembled within an abdominal aortic aneurysm.

Fig. 4A is a view of the delivery system for the main body of the endovascular graft, which forms a part of the system shown in Fig. 1.

Figs. 4B and 4C are views of the top and bottom of the control handle of the main body delivery system shown in Fig. 4A.

Fig. 4D is a view of the distal end of the main body delivery system shown in Fig. 4A, with parts broken away to show the attachment of the main body of the endovascular graft to the delivery system and the release wire and jacket controls that are coupled to the handle to affect a controlled stepwise release of the main body from the delivery system.

Fig. 4E is a view of the distal end of the main body delivery system showing the retracted and advanced positions of the slidable release jacket.

Fig. 5A is a view of the handle of the main body delivery system shown in Fig. 4A, with portions broken away to show a hemostatic seal assembly within the housing.

Figs. 5B and 5C are, respectively, exploded and assembled views of the hemostatic seal assembly shown in Fig. 5A.

Fig. 5D is an enlarged view of the hemostatic seal assembly within the handle of the main body delivery system, showing the passage of the release wires through the seal assembly between the control mechanisms and the distal end of the main body delivery system (as shown in

Fig. 4D).

Fig. 6A is a view of the delivery system for a lumen extension of the endovascular graft, which forms a part of the system shown in Fig. 1.

Figs. 6B and 6C are views of the top and bottom of the control handle of the lumen extension delivery system shown in Fig. 6A.

Fig. 6D is a view of the distal end of the lumen extension delivery system shown in Fig. 6A, with parts broken away to show the attachment of a lumen extension of the endovascular graft to the delivery system and the release wire and jacket controls that are coupled to the handle to affect a controlled release of the lumen extension from the delivery system.

Fig. 7A is a view of the steerable endovascular guide and obturator that form a part of the system shown in Fig. 1.

Fig. 7B is an enlarged view of the handle of the steerable endovascular guide shown in Fig. 7A.

Fig. 8A is a view of a endovascular fastener or staple that forms a part of the system shown in Fig. 1.

Figs. 8B and 8C are views of a cassette to hold the a plurality of endovascular fasteners, as shown in Fig. 8A, and to present the fasteners for loading in the staple applier, which also forms a part of the system shown in Fig. 1.

Fig. 9A is a view of a fastener applier for implanting a fastener as shown in Fig. 8A, which forms a part of the system shown in Fig. 1.

Fig. 9B is an enlarged view of the handle of the fastener applier shown in Fig. 9A.

Fig. 10A is a view showing the manipulation of the fastener applier shown in Fig. 9A in loading a fastener from the cassette shown in Figs. 8B and 8C.

Figs. 10B and 10C are anatomic views showing the

actuated element at the distal end of the fastener applier being driven to implant a fastener in a graft and adjacent tissue, to secure the position of the graft.

Fig. 11A is a view showing a fastener applier of a type shown in Fig. 9A, which includes indicia visable to a naked eye.

Fig. 11B is a view showing the fastener applier shown in Fig. 11A in association with a steerable endovascular guide of a type shown in Fig. 7A, showing how the indicia, which is visible to a naked eye, marks when the actuated member rests at a desired distance within the guide short of the terminus of the guide and therefore out of contact with tissue.

Fig. 11C shown the distal end of the guide when the indicia visible at the proximal end of the guide marks when the actuated member rests at a desired distance within the guide short of the terminus of the guide and therefore out of contact with tissue.

Figs. 12A to 12P are anatomic views of manipulation of the components of the system shown in Fig. 1 in placing a prosthesis in an abdominal aortic aneurism, which manipulations can be incorporated within an instruction for use associated with a kit like that shown in Fig. 2.

Fig. 13A is a schematic view of the motor control functions of a representative control circuit for the fastener applier shown in Fig. 9A.

Fig. 13B is a schematic flow diagram of the operational states of the control circuit shown in Fig. 13A.

Detailed Description

This Specification discloses various catheter-based devices, systems, and methods for delivering and implanting radially expandable prostheses in the body lumens. For example, the various aspects of the invention

have application in procedures requiring the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel. The devices, systems, and methods that embody features of the invention are also adaptable for use with systems and surgical techniques that are not necessarily catheter-based.

The devices, systems, and methods are particularly well suited for treating aneurysms of the aorta that primarily occur in the abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation, as well as aneurysms that also occur in the thoracic region between the aortic arch and renal arteries. For this reason, the devices, systems, and methods will be described in this context. Still, it should be appreciated that the disclosed devices, systems, and methods are applicable for use in treating other dysfunctions elsewhere in the body, which are not necessarily aorta-related.

When referring to an endovascular graft or its components that are intended to be implanted in a vessel or body organ, the terms "proximal" and "distal" will be used to describe the relation or orientation of the graft with respect to the heart after implantation. Therefore, the term "proximal" will be used to describe a relation or orientation of the graft that, when implanted, is toward the heart, and the term "distal" will be used to describe a position or orientation of the graft that, when implanted, is away from the heart, i.e., toward the feet.

When referring to implantation apparatus or devices that are manipulated by a physician or operator in order to implant the endovascular graft or its components, the terms "proximal" and "distal" will be used to describe the relation or orientation of the apparatus or device with respect to the operator as it is used. Therefore,

the term "proximal" will be used to describe a relation or orientation of the apparatus or device that, when in use, is positioned toward to the operator (i.e., at the handle end of the device), and the term "distal" will be used to describe a position or orientation of the apparatus or device that, when in use, is positioned away from the operator (i.e., at the other end of a catheter or the like away from the handle).

I. SYSTEM OVERVIEW

Fig. 1 shows a system 10 for repairing an endovascular aneurysm, which is well suited for the repair of an abdominal aortic aneurysm (AAA). The system 10 comprises three primary components 12, 14, and 16.

The first component 12 comprises an endovascular graft assembly. In use, the endovascular graft assembly 12 is placed within a vessel at the site of the aneurysm. In the illustrated embodiment, the endovascular graft assembly 12 includes a main body 18 that is placed within the aorta adjacent the renal arteries (see Fig. 3C), and lumen extensions 20 and 22 that extend into the contralateral and ipsilateral branches of the iliac artery, as Fig. 3C shows.

The second component 14 comprises an endovascular delivery system for introducing and deploying in sequence the main body 18 and lumen extensions 20 and 22 of the endovascular graft assembly 12 using an endovascular approach. In the illustrated embodiment, in which the endovascular graft assembly 12 comprises three modular portions - the main body 18, the ipsilateral lumen extension 20, and the contralateral lumen extension 22 - there are three corresponding endograft delivery components 24, 26, and 28.

The third component 16 comprises an endovascular stapling system. In use, the endovascular stapling system 16 attaches one or more regions of the endovascular graft

assembly to the vessel wall with one or more endovascular staples. In the illustrated embodiment, the endovascular stapling system 16 comprises a steerable endovascular guide 30, an obturator 32, a cassette 34 holding a plurality of endovascular staples 36, and an endovascular staple applier 38. In use, the steerable endovascular guide 30 establishes an endovascular path to the targeted site where the endovascular graft assembly 12 has been partially or fully deployed. The steerable endovascular guide 30 is manipulated by flexure and rotation to successive sites where individual endovascular staples 36 are to be implanted, to penetrate the endovascular graft assembly 12 and adjacent vessel wall. The endovascular staple applier 38, carrying one or more endovascular staples 36, is guided by the steerable endovascular guide 30 to the successive sites. The endovascular staple applier 38 is actuated to implant individual endovascular staples 36 into selected region or regions of the endovascular graft assembly 12 and adjacent vessel wall, to attach the endovascular graft assembly 12 to the vessel wall.

II. THE KIT

As Fig. 2 shows, the various tools and devices as just described, comprising the system 10, can be consolidated for use in a multiple piece functional kit 40.

The kit 40 can take various forms. In the illustrated embodiment, the kit 40 comprises an assemblage of individual packages 42, 44, 46, 48, 50, 52, 54, and 56, each comprising a sterile, wrapped, peel-open assembly. One or more the packages may include an interior tray made, e.g., from die cut cardboard, plastic sheet, or thermo-formed plastic material, which hold the contents. The kit 40 also preferably includes instructions or directions 58 for using the contents of

the packages to carry out a desired procedure. A desired procedure using the contents of the kit 40 shown in Fig. 2 will be described in greater detail later.

The instructions for use 58 can, of course vary. The instructions for use 58 can be physically present in one or more of the packages, but can also be supplied separately. The instructions for use 58 can be embodied in separate instruction manuals, or in video or audio recordings. The instructions for use 58 can also be available through an internet web page.

A. The Component Packages

The arrangement and contents of the packages can vary.

For example, as shown in Fig. 2, the kit 40 comprises eight packages 42, 44, 46, 48, 50, 52, 54, and 56. Five of these packages 42, 44, 46, 48, and 50 provide the main components of the endovascular repair system 10 as described. The remaining packages 52, 54, and 56 provide ancillary components used in the deployment of the system 10, e.g., conventional vascular access sheaths (in package 52); conventional 0.035 inch guide wires (in package 54); and bags containing heparinized saline for catheter flushing and contrast for angiography (in package 56).

In package 42, the main body 18 of the endovascular graft assembly 12 is preloaded into the main body endograft delivery components 24. In package 44, the ipsilateral lumen extension 20 of the endovascular graft assembly 12 is preloaded into the ipsilateral extension endograft delivery component 26. In package 46, the contralateral lumen extension 22 of the endovascular graft assembly 12 is preloaded into the contralateral extension endograft delivery component 28. Housed within the packages 42, 44, and 46, the components of the endovascular graft assembly 12 and the corresponding

delivery components 24, 26, and 28 for the endograft components are supplied sterile to the user.

As further shown in Fig. 2, the kit 40 comprises an additional package 50 that provides the steerable endovascular guide 30 and at least one associated components; namely, the obturator 32. The kit 40 also comprises an additional package 48 that provides the endovascular staple applier 38 and at least one associated component; namely, a cassette 34 holding a plurality of endovascular staples 36. Housed within the packages 48 and 50, the steerable endovascular guide 30 and the endovascular staple applier 38 and their associated components are supplied sterile to the user.

Further details of a representative construction of the contents of the packages will now be described.

1. The Endovascular Graft

a. The Main Body

In a representative embodiment (see Fig. 3A), the main body 18 of the endovascular graft is a multi-lumen endograft comprising two primary components: a graft 60 made of a biocompatible material, e.g., polyester, ePTFE, etc.; and one or more stents or scaffolds 62 made of a biocompatible metal or plastic material, e.g., Stainless steel, nickel-titanium (Nitinol), etc.

In a representative embodiment, the preferred length of the main body 18 is between 5 cm and 14 cm and most preferably between 7 cm and 10 cm. Desirably, different dimensions for the diameter of the main body 18 are provided to accommodate different anatomic dimensions of patients.

As illustrated, the multi-lumen endograft is a tube at the proximal end, which separates into two distal ipsilateral and contralateral lumens 64 and 66. The ipsilateral and contralateral lumens 64 and 66 are separated by a septum 68 or "shared wall" between them.

The septum 68 extends the length of the ipsilateral lumen 64 (in the representative embodiment, approximately 3 cm).

The main body 18 includes a proximal sealing stent 70, e.g., with diamond or "V" shaped cells, which is sewn to the inside proximal end of the graft e.g., with braided or monofilament suture. The proximal sealing stent 70 is sized and configured to ensure secure apposition to the vessel wall just below the renal arteries. The stent 70 preferably extends beyond the fabric 0 mm to 15 mm and most preferably extends 1 mm to 10 mm.

The main body 18 includes a distal locking stent 72 located in each of the two lumens 64 and 66 at the distal end of the main body 18. The stents 72 are sewn to the graft, e.g., with braided or monofilament suture. The distal locking stents 72 of the main body 18 engage with the tape covering the proximal spiral stent 86 on the lumen extensions 20 and 22 (see Fig. 3B) to help prevent component separation and provide support to the lumen openings of the main body 18.

Predetermined arrays of radiopaque markers made from biocompatible materials with high radiopacity (e.g, tantalum, platinum or gold) are desirably attached to the main body 18 to assist with visualization under fluoroscopy. The markers, like the stents, are sewn to the graft, e.g., with braided or monofilament suture or can be attached to the stent. The arrays can vary. In the illustrated embodiment, there are two (2) long contralateral side markers 74; three (3) short ipsilateral side markers 76; four (4) proximal stent marker bands 78; five (5) distal locking stent marker bands 80; and an insertion depth marker 82 near the proximal end of the septum 68 for positioning of the lumen extension.

Further details of representative constructions of the main body 18 of the endovascular graft assembly 12 can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,444, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including a Prosthesis Assembly," which is incorporated herein by reference.

b. The Lumen Extensions

In a representative embodiment (see Fig. 3B), each lumen extension 20 and 22 is sized and configured to be inserted into the corresponding ipsilateral and contralateral lumens of the main body 18, to complete the assembly of the endovascular graft 12 (see Fig. 3C). The lumen extensions 20 and 22 can be provided in various lengths and diameters to different anatomic dimensions of patients.

In a representative embodiment, each lumen extension comprises a biocompatible material 84, e.g., polyester, ePTFE, etc, and two stent or scaffold components 86 and 88 made of a biocompatible metal or plastic material, e.g., Stainless steel, nickel-titanium (Nitinol), etc.

The first stent component 86 comprises a continuous, spiral sinusoidal stent that runs the length of the lumen extension 20 and 22. The spiral stent component 86 is sized and configured to prevent kinking and maintain patency of the graft. The stent component can be sewn to the graft, e.g., with braided or monofilament suture. The proximal region of the spiral stent is further covered with material, e.g., polyester, ePTFE, etc. The covered proximal region 90 is sized and configured to engage the locking stent 72 in the main body 18 (see Fig. 3C) to prevent separation of the lumen extension from the main body 18. The covered proximal region 90 also serves to prevent the metallic stent components from coming into

contact with one another.

The other stent component 88 of each lumen extension comprises a distal sealing stent. The stent component 88 can be sewn to the graft, e.g., with braided or monofilament suture. The distal sealing stent 88 is sized and configured to ensure good apposition of the lumen extension to the wall of the iliac artery. The distal sealing stent 88 preferably extends beyond the distal end of the fabric portion of the lumen extension 0mm to 15mm and most preferably extends 1mm to 10mm.

Predetermined arrays of radiopaque markers made from biocompatible materials with high radiopacity (e.g, tantalum, platinum or gold) are desirably attached to each lumen extension to assist with visualization under fluoroscopy. The markers, like the stents, can be sewn to the graft, e.g., with braided or monofilament suture or can be attached to the stent. The arrays can vary. In the illustrated embodiment (Fig. 3B), there is a proximal insertion depth marker 92 at the proximal end of the graft material and a distal marker 94 at the distal end of the graft material.

Further details of representative constructions of the lumen extensions 20 and 22 of the endovascular graft assembly can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,444, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including a Prosthesis Assembly," which is incorporated herein by reference.

2. Endovascular Graft Delivery Components

a. The Main Body Delivery System

i. General Overview

The main body 18 of the endovascular graft assembly 12 is preloaded into the main body delivery system 24 (see Fig. 4A), which is a single use component that is

supplied to the user within its package 42 in a sterile condition (see Fig. 2). The main body delivery system 24 is sized and configured to facilitate accurate placement of the main body 18 of the endovascular graft assembly 12 and to allow the physician to maintain control of the main body 18 while the endovascular staples 36 are applied.

In the illustrated embodiment (see Fig. 4A), the main body delivery system 24 comprises a delivery catheter 96 and a control handle 98 coupled to the proximal end of the delivery catheter 96. The delivery catheter 96 (see Fig. 4D) comprises a flexible inner assembly 100 and an outer graft retention jacket 102. The inner assembly 100 carries at its distal-most end a flexible radiopaque tracking nosecone 104.

When preloaded (see Fig. 4D), the main body 18 of the endovascular graft assembly 12 is attached to the inner assembly 100 in three locations. Just proximal of the nosecone 104 (i.e., toward the handle 98), the main sealing stent 70 of the main body 18 is secured by a releasable suture S1 to the inner assembly 100. Also just proximal of the nosecone 104, the inner assembly 100 includes a set of main body stabilizing arms 106. In the illustrated embodiment, there are three stabilizing arms 106. The proximal end of the preloaded main body 18 of the endovascular graft assembly is attached to the three stabilizing arms by three releasable pull wires S2, each threaded through eyelets in a respective one of the distal ends of the stabilizing arms 106 and through adjacent graft material. The distal end of the ipsilateral lumen 66 of the preloaded main body 18 is also attached to the inner assembly 100 by a releasable suture S3. These sutures and release wires S1, S2, and S3 secure the main body 18 of the endovascular graft assembly 12 to the inner assembly 100 for deployment to

the targeted implantation site.

Separate wires 108, 110, and 112 extend from the handle 98 along the inner assembly 100. The separate release wires 108 and 112 are independently coupled to the sutures S1 holding the proximal sealing stent 70 (release wire 108) and the suture S3 at the distal end of the ipsilateral lumen 66 (release wire 112). The release wires 110 are continuations of the release wires S2 threaded through the stabilizing arms 106 (as previously described), so that, in the illustrated embodiment, there are actually three release wires 110, one for each arm 106. Controls 114, 116, and 118 on the handle 98 are coupled to the separate release wires 108, 110 (commonly coupled to the three wires), and 112, as will be described in greater detail later, to independently release the sutures or release wires at one location, without necessarily releasing the sutures or release wires at another location. The separate and independently controllable release wires 108, 110, 112 and make it possible to release of the main body 18 of the endovascular graft assembly 12 in a prescribed order, to deploy the main body 18 of the endovascular graft assembly 12 in a desired sequence during the graft deployment process, as will be described in greater detail later.

The graft retention jacket 102 is sized and configured to slide over and along the inner assembly 100 from an advanced position over the main body 18 of the preloaded endovascular graft assembly 12 (shown in phantom Lines in Fig. 4E) to a retracted position spaced away from the main body 18 of the preloaded endovascular graft assembly 12 (shown in solid lines in Fig. 4E). A radiopaque marker 120 is positioned at the leading edge of the graft retention jacket 102 to assist in visualization under fluoroscopy. A jacket control

mechanism 122 coupled to controls 124 and 126 on the handle 98 affects retraction of the graft retention jacket 102 in a stepwise fashion -- using first control 124 and then control 126, as will be described later -- as well as the re-advancement of the retention jacket 102 using the single control 126 after the main body 18 has been fully deployed and it is time to withdraw the delivery system.

When in its advanced position, the graft retention jacket 102 protects the preloaded main body 18 of the endovascular graft assembly 12 as it is advanced through the patient's vasculature. When in its retracted position, the graft retention jacket 102 frees the preloaded main body 18 of the endovascular graft assembly 12 for deployment by operation of the controls 124 and 126 on the handle 98 during the graft deployment process.

The actuating components on the control handle 98 (see Figs. 4B and 4C) include a jacket retraction knob 124 and a jacket retraction slide 126, which are coupled to the jacket control mechanism 122 just described (as shown in Fig. 4D). The jacket retraction knob 124 is actuated by rotation and is coupled to a rack and pinion component of the jacket control mechanism 122 within the handle 98. The rack and pinion component applies a mechanical advantage in response to rotation of the knob 124 sufficient to overcome the initial resistance of the graft retention jacket 102 to axial movement beyond the proximal sealing stent 70 of the main body 18 of the endovascular graft assembly 12. Once free of the proximal sealing stent 70, the rack and pinion component of the jacket control mechanism 122 is automatically released from the jacket retraction knob 124 (the knob 124 will accordingly spin freely), and subsequent control passes to the jacket retention slide 126. Pulling on the jacket retention slide 126 (which does not provide a mechanical

advantage) suffices to complete the retraction of the jacket 102. This control sequence provides the physician with tactile feedback during the retraction of the jacket 102. After retracted in this manner, the jacket 102 can be advanced back toward the nosecone 104 using the jacket slide 126 when it is time to withdraw the delivery system.

The actuating components on the control handle (see Figs. 4B and 4C) also include a proximal sealing stent release slide 114, a graft release slide 116, and an ipsilateral lumen release slide 118. The proximal sealing stent release slide 114 is coupled to the release wire 110 for the proximal sealing stent 70 (see Fig. 4D). The graft release slide 116 is coupled to the three separate release wires 110 for the stabilizing arms 106 (also shown in Fig. 4D). The ipsilateral lumen release slide 118 is coupled to the separate release wire 112 for the distal end of the ipsilateral lumen 66 (as further shown in Fig. 4D).

Once the graft retention jacket 102 is retracted (as just described), pulling on the proximal sealing stent release slide 114 opens the proximal sealing stent 70. Despite opening the proximal sealing stent 70, the proximal and ipsilateral ends of the main body 18 of the endovascular graft assembly 12 remain attached to the inner assembly 100 of the endovascular graft delivery system. The physician maintains control of the main body 18 of the endovascular graft assembly 12 for further final positioning and for the application of the staples 36, as will be described in greater detail later.

Once positioned in a desired location and/or after insertion or implantation of staples to secure the main body 12 to the vessel wall, pulling on the graft release slide 116 releases the proximal end of the main body 18 of the endovascular graft assembly 12 from the

stabilizing arms 106. Despite opening the proximal sealing stent 70 and the stabilizing arms, the physician still maintains control of the ipsilateral end of the main body 18 of the endovascular graft assembly, which remains attached to the inner assembly 100. Next pulling on the ipsilateral lumen release slide 118 opens and releases the ipsilateral lumen 66 from the delivery catheter 96.

If desired, and as shown in phantom lines in Fig. 4A, a stationary outer jacket 220 may be provided that extends for a distance from the proximal end of the handle 98 over the delivery catheter 96 (the jacket 102) slides within the stationary outer jacket 220). The stationary jacket 220 provides a seal interface with a hemostatic valve of the introducer sheath at the access site. The stationary jacket 220 can be made of a suitable medical grade plastic, such as Fluroinated Ethylene Propylene (FEP) as non-limiting example. The stationary outer jacket 220 provides column strength and lubricity to reduce friction during sliding actuation of the jacket 102.

The delivery catheter 96 is desirably sized to present a minimum diameter according to the diameter of the main body 18 of the endovascular graft assembly 12 it carries. The delivery catheter 26 is desirably sized and configured with a lumen accommodating conventional over-the-wire delivery within a patient's vasculature, e.g., using a conventional 0.035 or 0.038 inch guide wire. In representative embodiment, the overall length of the delivery catheter is preferably between 40 and 120 cm and most preferably between 50 and 90 cm.

Further details of representative constructions of a main body delivery system 24 can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,116, filed October 20, 2005, and entitled

"Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which is incorporated herein by reference.

ii. Hemostasis Control

In a representative embodiment (see Fig. 5A), the proximal end of the handle 98 (near the sliding controls 114, 116, and 118 just described) includes a hemostatic seal assembly 128. As Fig. 5D shows, a flush passage 130 (for conveying heparinized saline to flush the delivery catheter 96 prior to deployment) communicates with the space between the inner assembly 100 and jacket 102 through the hemostatic seal assembly 128. As Fig. 5D also shows, the individual release wires 108, 110, and 112 for the proximal sealing stent release slide 114, the graft release slide 116 (one release wire 110 for each stabilizing arm 106), and the ipsilateral lumen release slide 118, as previously described, also pass from the slide controls 114, 116, and 118 within the handle in a sealed fashion through the hemostatic seal assembly 128 for passage along the inner assembly 100 to the distal end of the delivery catheter 96, where they connect to their respective components, as previously described. The hemostatic seal assembly 128 allows flushing to occur and prevents blood, which can enter the space between the outer jacket 102 and the inner assembly 100 catheter tube during use, from entering the interior of the handle 98.

In the illustrated embodiment (see Figs. 5B and 5C), the hemostatic seal assembly 128 includes first and second substantially rigid seal components 132 and 134, made e.g. of an inert material. The first seal component 132 comprises a center post 136 and a collar 138 that extends radially from an end of the post 136. The collar 138 forms a mount for coupling the hemostatic seal assembly 128 within the confines of the handle 98, as Fig. 5D shows.

The center post 136 defines a passage that sealingly engages the flush passage 130 of the delivery catheter 96, to provide a fluid seal.

The second seal component 134 comprises an annular ring that fits about the post. As further shown in Figs. 5B and 5C, the hemostatic seal assembly 128 further includes an annular septum or gasket 140 that also fits about the post 136. When assembled, the gasket 140 is sandwiched between the second seal component 134 and the collar 138 of the first seal component 132. The gasket 140 is made of a soft material, like silicone rubber. The collar 138 and the second seal component 134 include coaxial through-holes or guide tubes 142 to accommodate passage of the various release wires 108, 110, and 112 through the annular gasket 140. The through-holes 142 act as bearing surfaces or guides for the release wires 108, 110, and 112 on opposite sides of the annular gasket 140.

The gasket 140 provides a dynamic fluid seal for the release wires 108, 110, and 112. The fluid seal is maintained even if a release wire becomes tensioned during use in a non-axial direction. The length and diameter of the bearing surfaces of the through holes 142 and the thickness of the annular gasket 140 can vary depending upon the diameter of the release wires 108, 110, and 112 and direction or angle the release wires 108, 110, and 112 make as they exit the bearing through holes 142, to prevent tear out or sawing of the material of the gasket 140.

b. The Lumen Extension Delivery System

Each lumen extension 20 and 22 of the endovascular graft assembly is preloaded into a lumen extension delivery system, respectively 26 and 28(see Fig. 6A), each of which is a single use component that is supplied to the user within its package 44 and 46 in a sterile condition. Each lumen extension delivery system 26 and 28

is sized and configured to facilitate accurate placement of its lumen extension 20 and 22 of the endovascular graft assembly 12.

In the illustrated embodiment (see Fig. 6A), each lumen extension delivery system 26 and 28 comprises a delivery catheter 144 and a control handle 146 coupled to the proximal end of the delivery catheter 144. The delivery catheter 144 (see Fig. 6D) comprises a flexible inner assembly 148 and an outer graft retention jacket 150. The inner assembly 148 carries at its distal-most end a flexible radiopaque tracking nosecone 152.

When preloaded (see Fig. 6D), the lumen extension 20 or 22 of the endovascular graft assembly is attached to the inner assembly 148 by a releasable suture S4 at the proximal end of the spiral stent 86. A release wire 154 extends from the handle 98 along the inner assembly 148 and is coupled to the suture S4 holding the proximal end of the spiral stent 86. A sliding control 156 on the handle 146 is coupled to the release wire 154 (as will be described in greater detail later), to release the suture S4 and thereby release of the lumen extension 20 or 22 of the endovascular graft assembly 12 from the inner assembly 148 during the graft deployment process, as will be described in greater detail later.

The graft retention jacket 150 is sized and configured to slide over and along the inner assembly 148 from an advanced position over the preloaded lumen extension 20 or 22 of the endovascular graft assembly 12 (shown in phantom Lines in Fig. 6D) to a retracted position spaced away from the preloaded lumen extension 20 or 22 of the endovascular graft assembly 12 (shown in solid lines in Fig. 6D). A radiopaque marker 158 is positioned at the distal end of the graft retention jacket 150 to assist in visualization under fluoroscopy. A control mechanism 160 coupled to a sliding control 162

on the handle 146 affects advancement and retraction of the graft retention jacket 150, as will be described later.

When in its advanced position, the graft retention jacket 150 protects the preloaded lumen extension 20 or 22 of the endovascular graft assembly 12 as it is advanced through the patient's vasculature. When in its retracted position, the graft retention jacket 150 frees the preloaded lumen extension 20 or 22 of the endovascular graft assembly 12 for deployment by operation of the sliding control 162 on the handle 98 during the graft deployment process.

The actuating components on the control handle 146 (see Figs. 6B and 6C) include a jacket retraction knob 162 (coupled to the jacket control mechanism 160) and a proximal spiral stent release slide 156 (coupled to the release wire 154 just described (as shown in Fig. 6D). Pulling on the jacket retraction slide 162 suffices to retract the jacket 150. Once the graft retention jacket 150 is retracted (as just described), pulling on the proximal spiral stent release slide 156 opens and releases the lumen extension 20 or 22 from the inner assembly 148.

A stationary outer jacket 220 may also be provided for the lumen extension delivery systems 26 and 28 (as shown in phantom lines in Fig. 6A). As previously described with respect top the main body delivery system 24, the stationary outer jacket 220 extends for a distance from the proximal end of the handle 146 over the delivery catheter 144 (the jacket 150) slides within the stationary outer jacket 220). The stationary jacket 220 provides a seal interface with a hemostatic valve of the introducer sheath at the access site. As previously described, the stationary jacket 220 can be made of a suitable medical grade plastic, such as Fluroinated

Ethylene Propylene (FEP) as non-limiting example. The stationary outer jacket 220 provides column strength and lubricity to reduce friction during sliding actuation of the jacket 150.

Each lumen extension delivery catheter 144 is desirably sized to present a minimum diameter according to the diameter of the lumen extension 20 or 22 of the endovascular graft assembly 12 it carries. The delivery catheter 144 is desirably sized and configured with a lumen accommodating conventional over-the-wire delivery within a patient's vasculature, e.g., using an appropriately sized guide wire. In representative embodiment, the over-all length of the lumen extension delivery catheter 144 is preferably between 40 and 120 cm and most preferably between 50 and 90 cm.

The lumen extension delivery catheter can include a hemostatic valve assembly of the type previously described and as shown in Figs 5A to 5D.

Further details of representative constructions of a lumen extension delivery system can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,116, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which is incorporated herein by reference.

c. Endovascular Stapling System

The endovascular stapling system 16 comprises steerable endovascular guide 30 and a companion obturator 32 (see Figs. 7A and 7B) for over-the-wire, intravascular deployment of the steerable endovascular guide 30. The endovascular stapling system 16 also comprises a plurality of endovascular staples 36 (Fig. 8A) and, desirably, a cassette 34 for holding the staples 36 (see Fig. 8B), as well as an endovascular staple applier 38 (see Figs. 9A and 9B).

d. Steerable Endovascular Guide and Companion Obturator

The steerable endovascular guide 30 is a single use component that is supplied with a companion obturator 32 to the user within its package 50 in a sterile condition. The steerable endovascular guide 30 is sized and configured to direct the endovascular staple applier 38 to the desired location for implantation of one or more endovascular staples 36.

The steerable endovascular guide 30 (see Figs. 7A and 7B) includes a guide tube 164 and a handle 166 coupled to the proximal end of the guide tube 164. The guide tube defines an open interior lumen 168 accommodating passage of the obturator 32 (during deployment) and the endovascular staple applier 38 (during use).

The distal portion of the guide tube 164 can be deflected in one direction (as shown in phantom lines in Fig. 7A) and straightened by a steering wire (not shown) coupled to a rotational deflector knob 170 on the handle 166. In a representative embodiment, the over-all length of guide tube 164 and handle 166 is preferably between 40 and 120 cm and most preferably between 50 and 90 cm, and the length of the deflectable tip is preferably between 1 and 10 cm and most preferably between 2 and 5 cm. A C-shaped radiopaque marker 172 is located at the distal tip of the guide tube 164 to aid in orientation under fluoroscopy.

In a representative embodiment, the obturator 32 is desirably sized and configured with a lumen 174 accommodating conventional over-the-wire delivery within a patient's vasculature, e.g., using an appropriately sized guide wire.

Further details of representative constructions of a steerable endovascular guide 30 can be found in co-

pending, commonly owned United States Patent Application Serial No. 11/254,619, filed October 20, 2005, and entitled " Devices, Systems, and Methods for Guiding an Operative Tool into an Interior Body," and co-pending, commonly owned United States Patent Application Serial No. 11/254,116, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which are both incorporated herein by reference.

B. The Endovascular Staple and Companion Cassette

The endovascular staple 36 (see Fig. 8A) is a single use component that is supplied, desirably in a companion cassette, to the user within a package in a sterile condition. The endovascular staple 36 is sized and configured to attach the endovascular graft assembly 12 to a vessel wall.

In the illustrated embodiment (see Fig. 8A) the endovascular staple 36 comprises a main staple body 176 that is helical-shaped. The helical-shape allows the endovascular staple 36 to pierce and engage tissue in response to rotation of the main staple body 176, thereby securing attachment of the endovascular graft assembly 12 to a vessel wall.

In a representative embodiment, the main staple body 176 is manufactured from medical grade wire having a diameter of from .1 mm to 1 mm. In a representative embodiment, the endovascular staple 36 is approximately between 2 mm to 12 mm in over-all length and approximately from approximately 1 mm to 10 mm in maximum diameter. The leading end 178 of the main staple body 176 is desirably sharpened to facilitate atraumatic deployment through the graft materials and vessel wall. The proximal end 180 of the main staple body 176 is desirably closed to prevent over-penetration of the endovascular staple 36.

Desirably, a plurality of staples 36 (e.g., ten) are provided in a cassette 34 (see Fig. 8B), to allow easy and accurate loading into the endovascular staple applier 38. The cassette 34 includes a base 208 having a plurality of spaced apart staple ports or stations 210, each sized to house a staple 36. A cover 212 rotates on the base 208 (see Fig. 8C). The cover 212 overlies the ports 210, closing them, except for an open notch region 214, which permits access to a single one of the ports 210. In use, an operator rotates the cover 212 to expose one port 210 and the staple 36 it contains. The operator operates the staple applier 38 to load the staple 36 from the exposed port 210, as will be described in greater detail. After implanting the withdrawn staple 36, the operator rotates the cover 212 to expose another one of the ports 210 and the staple 36 it contains. The operator again operates the staple applier 38 to load the staple 36 from the exposed port 210 for implantation. In this way, the cassette 34 aids the operator in loading individual staples on the staple applier 36 for implantation in a single fire (one at a time) fashion.

Further details of representative constructions of an endovascular staple 36 and companion cassette 34 can be found in co-pending, commonly owned United States Patent Application Serial No. 11/255,116, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which is incorporated herein by reference.

C. Endovascular Staple Applier

1. Overview

The endovascular staple applier 38 (see Figs. 9A and 9B) is a single use component that is supplied to the user within a package 48 in a sterile condition. In the illustrated embodiment, the endovascular staple applier 38, a supply of endovascular staples 36, and the staple

cassette 34 are provided, for the sake of convenience, in a single package 48. The endovascular staple applier 38 is sized and configured to pass through the lumen 168 of the steerable endovascular guide tube 164 and to be selectively operated to implant one or more endovascular staples 36 through the graft materials and vessel wall.

In the illustrated embodiment, the endovascular staple applier 38 comprises an applier catheter 182 and a control handle 184 coupled to the end of the applier catheter 182. The applier catheter 182 carries a rotationally driven member 186 at its distal end. A battery powered motor 188 enclosed within the handle 184 is coupled to the driven member 186, to selectively rotate the driven member 186 either in a forward (e.g., clockwise) direction and reverse (e.g., counterclockwise) direction. A control circuit 190 in the handle 184 is coupled to the motor 188 and to a forward control button 192 and a reverse control button 194 on the handle. The control circuit 190 governs operation of the operation of the motor 188 according to pre-programmed operating parameters in response to user commands received by manipulation of the buttons 192 and 194.

In use (see Figs. 10A to 10H), an endovascular staple 36 is loaded into the driven member 186 from the cassette 34, e.g., by placing the distal end of the applier catheter 182 into an exposed staple port 210 in the cassette 34 and pressing the reverse control button 194 (Fig. 10A). The now loaded endovascular staple applier 38 is passed through the guide tube 164 of the endovascular guide 30 (Fig. 10B), which has been manipulated beforehand to be at an intended implantation site for the endovascular staple 36.

Once the endovascular staple applier 38, loaded with a staple, is positioned at the desired location (Fig. 10C), the physician presses the forward control button

192 to command rotation of the endovascular staple 36 in the forward direction (i.e., into tissue).

The control circuit 190 is desirably pre-programmed to require a two-stage implantation process. The first stage commands only a partial implantation of the staple 36. In the first stage, the physician is allowed to ascertain whether the staple 36 is placed correctly at the desired location and that the desired located is suitable for implantation of the staple 36. While in the first stage, the physician is allowed to retract the staple 36 (by pressing the reverse control button 194) and to re-position the staple 36.

The control circuit 190 commands a full final deployment of the staple 36 only after a deliberate entry of the second stage. In the first and second stages, the control circuit 190 generates audible tones and visual indicators e.g., blinking lights, during operation of the motor 188, to indicate the position of the staple and available direction of motion.

Once the staple 36 is implanted, the endovascular staple applier 38 is withdrawn through the endovascular guide. The cassette cover 212 is rotated to reveal another staple port 210 and the staple 36 it contains. The staple applier 38 is reloaded. The endovascular guide 30 is manipulated to another desired implantation site, and the endovascular staple applier 38 (reloaded with another staple 36) is redeployed and operated in the manner just described. The endovascular staple applier 38 is intended to be loaded, deployed, and reloaded in this way multiple times for a single patient.

Further details of representative constructions of an endovascular staple applier 38 and methods of its use can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,950, filed October 20, 2005, and entitled "Devices, Systems, and Methods for

Prosthesis Delivery and Implantation, Including the Use of a Fastening Tool" which is incorporated herein by reference.

2. Tracking the Relative Position of the Endovascular Staple Applier in the Endovascular Guide

Desirably, the endovascular staple applier 38 includes indicia 196, which is visible to a naked eye (i.e., without resort to fluoroscopic visualization or other visualization techniques that augment human vision) the indicates the extent to which the driven distal end 186 of the applier catheter 182, which carries the endovascular staple 36, resides within the guide tube 164 of the steerable endovascular guide 30. In particular, the visible indicia 196 indicates when the driven distal end 186 of the applier catheter 182 and the staple 36 it carries have arrived at a predetermined location within the guide tube near to but still within the distal end of the guide tube 164. In this way (see Fig. 11C), the physician can quickly and accurately ascertain, without resort to fluoroscopic visualization, that the distal end of the applier catheter 182, and the endovascular staple 36 it carries, are positioned wholly within the confines of the guide tube 164, ready for final deployment, once the guide tube 164 is placed at the intended implantation site. The visible indicia 196 can also indicate to extend to which the driven distal end 186 of the applier catheter 182 has been extended outside the distal end of the guide tube 164.

In the illustrated embodiment (see Fig. 11A), the indicia 196 comprises visible material or markings on the most proximal section of the applier catheter 182, adjacent the handle 184, that is marked or colored differently or is otherwise differentiated from the remainder of the applier catheter 182. In a

representative example, a prescribed length of contrast-colored tubing 198 can be placed at the most proximal end of the applier catheter 182, where it exits the handle 184.

The contrast-color tubing 198 has a prescribed length. The distal end of the tubing 198 marks a line of differentiation between the tubing 198 and the remainder of the applier catheter 182. The length is selected so that the distal end of the tubing 198 registers with the insertion port/hemostatic seal 200 on the handle 166 of the steerable endovascular guide 30 (see Fig. 11B) when the driven distal end 186 of applier catheter 182 rests at a desired inset distance d within the distal end of the guide tube 164 (see Fig. 11C).

In this way, the indicia 196 indicates when the applier catheter 182 has reached a desired insertion depth within the guide tube, and is ready to be further advanced beyond the guide tube 164 to implant the endovascular staple 36. The contrast-color tubing 198 may further include additional markings M along its length by which the physician can gauge advancement of the applier catheter 182 beyond the endovascular guide 20.

The indicia 196 makes it possible for the physician, without resort to fluoroscopic visualization, to always know whether the endovascular staple 36 is within or outside the endovascular guide 30.

3. The Motor Control Circuit

In a representative embodiment (see Fig. 13A), the control circuit 190 for the motor includes an optical encoder 250 coupled to a counting function 252, to enable counting the revolutions of the battery powered motor 188. The control circuit 190 also includes a sensing function 254 that senses the magnitude of current being drawn by the motor 188, for deriving torque that the motor 188 is encountering. The control circuit 190 also

includes a comparison function 256 that compares the magnitude of the sensed torque (current) with set torque limits in either the forward or reverse direction, to change the state of operation should excess torque conditions be encountered.

The control circuit 190 carries embedded code, which expresses pre-programmed rules or algorithms under which different operation states are entered and motor command signals are generated in response to input from the external control sources and the counting, sensing, and comparison functions. The pre-programmed rules or algorithms of the control circuit 190 are designed to conserve power consumption, placing the circuit into a standby (wait) mode between staple loading and deployment cycles. This makes it possible to power up the staple applier just once and to leave the staple applier on during an entire procedure, avoiding time consumed in repeated power ups and power downs. The pre-programmed rules or algorithms of the control circuit also dictate that a desired sequence of steps is faithfully followed in loading, deploying, and reloading the staples, prompting the physician at the initiation of each step and not allowing any short-cuts or deviations along the way.

Features of the pre-programmed rules or algorithms of a representative control circuit 190 for the staple applier will now be described in greater detail.

POWER UP/SYSTEM SELF-CHECK

In a representative implementation (see Fig. 13B), the pre-programmed rules or algorithms of the control circuit 190 enter a POWER UP state when an operator enters a prescribed power up command, e.g., when the operator presses and holds the reverse control button 194 for a prescribed amount of time. In the POWER UP state, the pre-programmed rules or algorithms of the control

circuit 190 first check battery voltage against a set minimum. The POWER UP state proceeds if the battery voltage exceeds the set minimum. Otherwise, the pre-programmed rules or algorithms of the control circuit 190 enter a LOW BATTERY FATAL state.

Absent a LOW BATTERY FATAL state, the pre-programmed rules or algorithms of the control circuit 190 enable the optical encoder and drive the motor 188 in a forward direction for a set period of time. The counting and sensing functions of the control circuit 190 count the number of revolutions and sense forward current. If the forward current exceeds a set maximum current level (as determined by the comparison function), the pre-programmed rules or algorithms of the control circuit 190 enter a FORWARD TORQUE FATAL state. Otherwise, the sensed forward current is registered by the pre-programmed rules or algorithms of the control circuit 190 as a base line for forward torque.

Absent a FORWARD TORQUE FATAL state, the pre-programmed rules or algorithms of the control circuit 190 enable the optical encoder and counting function, and drive the motor 188 in a reverse direction for a set period of time. The counting function of the control circuit 190 counts the number of revolutions, while the sensing function senses reverse current. If the reverse current exceeds a set maximum current level (as determined by the comparison function), the pre-programmed rules or algorithms of the control circuit 190 enter a REVERSE TORQUE FATAL state. Otherwise, the sensed reverse current is registered by the pre-programmed rules or algorithms of the control circuit 190 as a base line for reverse torque.

Audible tones and visual indicators (e.g. blinking lights) coupled to the control circuit 190 desirably accompany the POWER UP state as the system self-check is

accomplished. If no fatal states are encountered during the POWER UP sequence, the pre-programmed rules or algorithms of the control circuit 190 enter a READY TO LOAD state. The pre-programmed rules or algorithms of the control circuit 190 enable a ready to load prompt, e.g., blinking a reverse green arrow 202 (see Fig. 9B), to indicate to the user that the endovascular staple applier 38 is ready to load the first endovascular staple. If a fatal state is encountered, the pre-programmed rules or algorithms of the control circuit 190 enable a different prompt, e.g., illuminating a red error light 204 (see Fig. 9B), indicating that the endovascular staple applier 38 has encountered an error.

In addition, there are other checks that can be performed during the POWER UP state, including checking the encoder and the watchdog function for operation.

In a representative implementation, the pre-programmed rules or algorithms of the control circuit 190 allow the operator to clear the error state one time, e.g., by pressing the forward control button 192. After the error has been cleared, the self-check sequence of the POWER UP state will reinitiate. If during the second self check sequence, a fatal state is again encountered, the pre-programmed rules or algorithms of the control circuit 190 either disable the endovascular staple applier 38 from use, or again enable the error prompt. In the latter instance, the instructions for use 58 desirably will inform the operator not to use an endovascular staple applier 38 that has encountered a start-up error twice.

READY TO LOAD STATE: LOAD STAPLE

After the staple applier has been powered up and is in the READY TO LOAD state, the operator is able to load the endovascular staple by initiating a prescribed input command, e.g., by pushing the reverse control button 194.

The distal end of the endovascular staple applier catheter 182 is intended to be inserted into a staple port of the cassette at the time the input command is given.

When the prescribed input command is received, the pre-programmed rules or algorithms of the control circuit 190 command the motor 188 to rotate in a reverse direction for a set time period and generates a confirmation output with visual indicators (e.g., blinking the reverse green arrow 202). The endovascular staple 36 will be drawn from the cassette 34 into the distal end of the staple applier 38.

The sensing function of the control circuit 190 senses the magnitude of the current drawn by the motor 188 as the staple 36 is being loaded onto the distal end of the staple applier 38. Once a prescribed amount of current has been reached, the pre-programmed rules or algorithms of the control circuit 190 consider the staple applier to have completed the loading state. The pre-programmed rules or algorithms of the control circuit 190 then automatically go into a UNWIND sequence, to reduce or eliminate amount of torque windup in the staple applier catheter and drive shaft developed during the LOAD state. The pre-programmed rules or algorithms of the UNWIND sequence run the motor in the reverse direction from the load direction a set number of turns and wait for a command input.

After the UNWIND sequence, the endovascular staple is presumed loaded, and the pre-programmed rules or algorithms of the control circuit 190 enter a READY TO APPLY state. The pre-programmed rules or algorithms of the control circuit 190 generate a confirmation output, e.g., audible and visual indicators (e.g., two short beeps and a forward green arrow 206 will blink (see Fig. 9B) to prompt the next step, which is to deploy the

staple 36.

The endovascular staple 36 is now loaded in the staple applier 38, and the applier 38 can be removed from the cassette 34. The physician is desirably urged by the instructions for use 58 to verify that the endovascular staple 36 is in place by visually inspecting the distal end of the applier 38.

When the staple applier 38 has been powered up and is in the READY TO LOAD state, the pre-programmed rules or algorithms of the control circuit 190 desirably do not accept any command other than the command prescribed for loading (e.g., pushing the reverse control button 194). If an operator provides a contrary command, e.g., by pushing on the forward command button 192, the pre-programmed rules or algorithms of the command circuit will ignore the command. In this way, the pre-programmed rules or algorithms of the command circuit require an operator to follow a prescribed sequence in operating the staple applier.

READ TO APPLY STATE: DEPLOY STAPLE

When the pre-programmed rules or algorithms of the control circuit 190 have entered the READY TO APPLY state, and the operator is ready to deploy the staple 36, the operator is able to deploy the endovascular staple 36 by initiating a prescribed input command, e.g., by pressing the forward control button 192. When the forward control button 192 is pushed, the pre-programmed rules or algorithms of the control circuit 190 command the motor 188 to rotate in a forward direction for a set number of rotations (sensed by the counting function), which, according to the pre-programmed rules or algorithms, are less than the number of rotations required to fully implant the staple. The pre-programmed rules or algorithms of the control circuit 190 suspend operation of the motor 188 at this point and await another input

command. Thus, the pre-programmed rules or algorithms of the control circuit 190 only partially deploy the staple and generate a confirmation output, e.g., four beeps and/or alternatively blinking the forward and reverse arrows 202 and 206, prompting the operator to make a choice. This indicates that the operator may chose to continue deployment or to withdraw the endovascular staple back into the applier.

If the operator inputs a prescribed withdraw command, e.g., by pushing the reverse control button 194, the pre-programmed rules or algorithms of the control circuit 190 drive the motor 188 in the reverse direction for a set number of rotations (sensed by the counting function), to withdraw the staple 36. The pre-programmed rules or algorithms of the control circuit 190 then return to the READY TO APPLY state.

If the operator inputs a prescribed complete the implantation command, e.g. by pushing the forward control button 192, the pre-programmed rules or algorithms of the control circuit 190 will drive the motor 188 in the forward direction for a set number of rotations (monitored by the counting function), to complete the implantation of the staple. The pre-programmed rules or algorithms of the control circuit 190 generate a confirmation output, e.g., audio and visual indicators. The pre-programmed rules or algorithms of the control circuit 190 return to the READY TO LOAD state.

During the different operational states, the pre-programmed rules or algorithms of the control circuit 190 continue to check battery voltage against a set minimum. The operational states proceed as described as long as the battery voltage exceeds the set minimum. If, during an operational state the battery voltage falls below the set minimum, the pre-programmed rules or algorithms of the control circuit 190 enter a LOW BATTERY FATAL state.

D. The Instructions for Use

The instructions for use 58 can direct use of catheter-based technology via a peripheral intravascular access site, such as in the femoral artery, optionally with the assistance of image guidance. Image guidance includes but is not limited to fluoroscopy, ultrasound, magnetic resonance, computed tomography, or combinations thereof.

Figs. 12A to 12P show a representative embodiment of the steps that a representative instructions for use 58 can incorporate or direct.

In a representative embodiment, the instructions for use 58 may include the achievement of percutaneous vascular access by conventional methods into the femoral artery, for example. In this arrangement, the patient is placed on an imaging table, allowing fluoroscopic visualization from the aortic arch to the femoral artery bifurcations. Access is secured to both contralateral and ipsilateral branches by standard techniques using introducer sheaths (which can be supplied as part of the kit 40). Using fluoroscopic guidance, access to the patient's abdominal aorta can be achieved with an appropriately sized guide wire through each femoral access sites.

1. Position the Main Body Graft Assembly in the Targeted Endovascular Treatment Site

In this arrangement, the instructions 58 for use may include positioning of the main body 18 of the endovascular graft assembly to be deployed. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include:

(i) after flushing the main body delivery system 24 with heparinized saline, positioning the main body delivery system 24 within an aortic aneurysm over the

guide wire via the ipsilateral femoral access site, which has been previously established in conventional fashion (Fig. 12A);

(ii) visualizing the proper rotation and orientation of the main body 18 using the ipsilateral and contralateral radiopaque markers on the main body 18. As previously described, the main body 18 includes three (3) short markers 76 on the ipsilateral side and two (2) long markers 74 on the contralateral side for this purpose. The two rows of markers 74 and 76 should be parallel to each other and not cross. The main body delivery system 24 can be rotated for re-alignment of the main body 18 of the graft assembly 12.

(ii) withdrawing the graft retention jacket 102 of the main body delivery system 24 by rotating the jacket retraction knob 124, until the knob 124 spins freely (which indicates that the rack and pinion mechanism has been released). This step only partially retracts the jacket 102 (about 63 mm), unsheathing the proximal stent 70, with the remaining portion of the main body 18 still constrained within the jacket 102. The instructions may note that the proximal sealing stent 70 will not open during retraction of the jacket 102.

(iii) completing the retraction of the graft retention jacket 102 by sliding the jacket retention slide 126 away from the patient. The instructions may note that the contralateral lumen of the main body 18 is now fully open, while the proximal sealing stent 70 and ipsilateral lumen remain collapsed and connected to the main body delivery system 24 (Fig. 12B);

(iv) verifying the position and orientation of the main body 18 using the radiopaque markers 74 and 76, to ensure that blood flow to the renal arteries is not obstructed and the main body 18 of the graft assembly 12 is not twisted; and

(v) opening the proximal sealing stent 70 by retracting the proximal sealing stent release slide 114 (Fig. 12C). The instructions may note that the proximal and distal ends of the main body 18 of the endovascular graft assembly 12 still remain secured to the main body delivery system 24. The physician thereby maintains control of the position and orientation of the main body 18 of the graft assembly 12.

2. Deploy Endovascular Staples to Secure the Position of the Main Body of the Graft Assembly

The instructions for use 58 may next instruct securing of the position of the proximal end of the main body 18 of the endovascular graft assembly using endovascular staples 36. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include:

(i) placing an exchange length appropriately sized guide wire via the contralateral femoral access site into the abdominal aorta (Fig. 12D). The main body 18 of the endovascular graft assembly includes distal end radiopaque markers that outline the opening of the contralateral lumen of the main body 18. The guide wire is to be placed through this opening and its position verified using standard endovascular techniques.

(ii) inserting the obturator 32 into the lumen 168 of the steerable endovascular guide 30.

(iii) using fluoroscopic guidance, advancing the steerable endovascular guide 30 with the obturator 32 over the guide wire into a position within the proximal neck of the aortic aneurism (Fig. 12E). The C-shaped radiopaque marker 172 located at the distal tip of the steerable endovascular guide 30 will aid in fluoroscopic visualization.

(iv) removing the guide wire.

(v) removing the obturator 32 to open the lumen 168 of the steerable endovascular guide 30 for passage of the endovascular staple applier 38.

(vi) deflecting the distal end of the steerable endovascular guide 30 toward the first intended staple implantation area by rotating the deflector knob, while observing with fluoroscopic guidance. The instructions may note that the C-shaped fluoroscopic marker 172 will appear as a straight line when the catheter is oriented laterally, as a right curve "(" when oriented anteriorly, and as a left curve ")" when oriented posteriorly.

(vii) turning on the endovascular staple applier 38 by pressing and holding the reverse control button 194 for at least five (5) seconds. This initiates a self-checking sequence with audible tones and blinking lights. At the end of this sequence, the reverse green arrow 202 will be blinking, indicating that the endovascular staple applier 38 is ready to load the first endovascular staple 36. The instructions may note that, if at the end of the self check sequence, the red error light 204 is illuminated, the endovascular staple applier 38 has encountered an error. The error can be cleared by pressing the forward control button 192. After the error has been cleared, the self check sequence will initiate. If at the end of the second self check sequence, the red error light 202 is still illuminated, the endovascular staple applier 38 is not functional and should not be used.

(viii) after flushing the inner lumen of the endovascular staple applier 38 with heparinized saline via the flush port, loading the staple by pressing the reverse command button 194 on the handle. While the motor 188 is running, insert the distal end of the endovascular staple applier catheter 182 into the open staple port of the cassette 34. The reverse green arrow 202 will blink,

and the endovascular staple will be drawn from the cassette into the distal end of the staple applier 38. When the endovascular staple 36 is loaded, an audible tone (e.g., two short beeps) will be heard, and the forward green arrow 206 will blink. This indicates that the endovascular staple 36 is now preloaded in the staple applier 38, and the applier 38 can be removed from the cassette 34. The instructions may urge the physician to verify that the endovascular staple 36 is in place by visually inspecting the distal tip of the applier 38.

(ix) while stabilizing the control handle 166 of the endovascular guide 30 relative to the patient, inserting the now-loaded endovascular staple applier 38 through the hemostatic seal at the proximal end of the steerable endovascular guide control handle 166. The instructions may direct the physician to observe the location of the visible contrast-color tubing 198 or other indicia on the proximal end of the applier catheter 182 and to halt further insertion of the staple applier 38 when the end of the contrast-color tubing 198 registers with the insertion port/hemostatic seal on the handle of the steerable endovascular guide (as shown in Fig. 11B). This indicates that the distal end of applier catheter 182 rests in a desired short inset distance within the distal end of the guide tube 164 (as shown in Fig. 11C).

(x) inserting and positioning the steerable endovascular guide 30 at the desired location for endovascular staple implantation within a desired stapling zone, e.g., between the marker bands on the proximal sealing stent 70 and the bottom edge of the proximal sealing stent 70. The instructions may note that the endovascular staples should be evenly distributed around the circumference of the proximal sealing stent 70, typically about 4 to 6 endovascular staples per graft.

(xi) under fluoroscopic guidance, advancing the endovascular staple applier 38 through the steerable endovascular guide 30 until the endovascular staple applier 38 emerges from the distal end and contacts the endovascular graft assembly 12. Slowly, continue to advance the endovascular staple applier 38 until resistance is felt, indicating that the endovascular staple applier 38 is firmly pushing against the main body 18 of the endovascular graft assembly 12 against the vessel wall.

(xii) using the control handle 184 of the endovascular staple applier 38, pressing the forward control button 192 for achieving the first stage of endovascular staple deployment. The endovascular step will partially deploy and pause. An audible tone is heard (e.g., four beeps) and the forward and reverse arrows 202 and 206 will alternatively blink, indicating that the operator may continue deployment or withdraw the endovascular staple 36 back into the applier 38. The instructions may note that, in the event of a power loss when the staple 36 is partially deployed, the staple may be removed by manually rotating the handle 184 and catheter 182 in a counter-clockwise direction until the staple 36 disengages from the graft and tissue. The staple applier 38 can be removed from the endovascular guide 30 in this condition.

(xiii) If the endovascular staple 36 is not in the desired location, pressing the reverse control button 194 to re-house the staple inside the staple applier 38 for re-positioning.

(xiv) If the endovascular staple 36 is in the desired position, completing the final stage of staple deployment by pressing the forward control button 192 (Fig. 12F). When complete, an audible tone (e.g., three beeps) is heard and the reverse green arrow 202 will be

blinking.

(xv) using fluoroscopy, carefully and slowly retracting the endovascular staple applier 38 away from the graft wall to ensure it is released from the deployed staple.

(xvi) removing the endovascular staple applier 38, leaving the steerable endovascular guide 30 in place.

(xvii) using fluoroscopy, visually confirming that the endovascular staple 36 is in place.

(xviii) as needed, flush the steerable endovascular guide and the staple applier with heparinized saline to prevent clotting in the lumens.

(xix) rotating the head of the cassette 34 (as shown in Fig. 8C) clockwise to expose the next endovascular staple port. Load the next endovascular staple in the manner described above.

(xx) repositioning the steerable endovascular guide 30 to the next desired implantation site for an endovascular staple 36. Desirably, the physician straightens the steerable endovascular guide 30 between rotating in within the main body 18, to prevent accidental dislodgment or movement of the main body 18.

(xxi) deploying the next endovascular staple 36 through the steerable endovascular guide 30 in the manner described above. Typically, 4 to 6 endovascular staples, evenly distributed about the circumference of the main body 18, will serve to secure the position of the main body 18 within the vessel (Fig. 12G).

(xxii) after deployment of the last endovascular staple, removing the endovascular stapler applier 38 from the steerable endovascular guide 30.

(xxiii) re-advancing the obturator 32 and then the guide wire into the steerable endovascular guide.

(xxiv) removing the steerable endovascular guide 30 and the obturator 32, leaving the guide wire in position.

3. Deploy the Contralateral Lumen Extension

The instructions for use 58 may next include the deployment of the contralateral lumen extension 22 of the endovascular graft assembly. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include:

(i) after flushing with heparinized saline, advancing the contralateral lumen extension delivery system 28 over the guide wire in the contralateral femoral access site (Fig. 12H).

(ii) using fluoroscopic guidance, aligning the proximal marker 94 on the lumen extension 22 with the insertion depth marker 92 located medially on the main body 18.

(iii) holding the lumen extension deliver system 28 stable relative to the patient, retracting the jacket retraction slide 162 away from the patient to unsheath the lumen extension 22 (Fig. 12I). The distal end of the lumen extension 22 will deploy. The proximal end of the lumen extension 22 will remain collapsed and secured to the delivery system 28.

(iv) retracting the proximal stent release slide 156 to release the proximal end of the lumen extension 22 and complete the deployment of the lumen extension (Fig. 12J).

(v) rejacketing the lumen extension delivery system by holding the jacket retention slide 162 and slowly retracting the delivery system 28, until the nosecone seals into the proximal end of the jacket 150.

(vi) maintaining forward pressure on the jacket retention slide 162, removing the lumen extension delivery system 28 from the patient, leaving the guide wire and femoral access introducer sheath in place.

4. Complete the Deployment of the Main Body

The instructions for use 58 may next include the

completion of the deployment of the main body 18 of the endovascular graft assembly, which remains in a secured but partially deployed condition during the deployment of the contralateral lumen extension 22, as above described. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include:

(i) moving to the ipsilateral femoral access site, where the main body delivery system 24 resides.

(ii) releasing the stabilizing arms 106 from the graft by retracting the graft release slide 116 on the handle of the delivery system away from the patient (Fig. 12K).

(iii) releasing the main body ipsilateral lumen from the delivery system by retracting the ipsilateral release slide 118 on the handle away from the patient (Fig. 12L). The main body 18 is now fully released (Fig. 12K).

(iv) rejacketing the main body delivery system 24 by holding the jacket retention slide 126 and slowly retract the main body 18 delivery system, until the nosecone seals into the proximal end of the jacket 102.

(vi) maintaining forward pressure on the jacket retention slide 126, remove the main body delivery system 24 from the patient (Fig. 12L), leaving the guide wire and femoral access introducer sheath in place.

5. Deploy the Ipsilateral Lumen Extension

The instructions for use 58 may next include the deployment of the ipsilateral lumen extension 20 of the endovascular graft assembly 12. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include:

(i) after flushing with heparinized saline, advancing the ipsilateral lumen extension delivery system 26 over the guide wire in the ipsilateral femoral access

site (Fig. 12M).

(ii) using fluoroscopic guidance, aligning the proximal marker 92 on the lumen extension 20 with the insertion depth marker 82 located medially on the main body 18.

(iii) holding the lumen extension deliver system stable relative to the patient, retracting the jacket retraction slide 162 away from the patient to unsheath the lumen extension 20 (Fig. 12N). The distal end of the lumen extension 20 will deploy. The proximal end of the lumen extension 20 will remain collapsed and secured to the delivery system 26.

(iv) retracting the proximal stent release slide 156 to release the proximal end of the lumen extension 20 and complete the deployment of the lumen extension (Fig. 12O).

(v) rejacketing the lumen extension delivery system 26 by holding the jacket retention slide 162 and slowly retracting the delivery system 26, until the nosecone seals into the proximal end of the jacket 150.

(vi) maintaining forward pressure on the jacket retention slide 162, removing the lumen extension delivery system 26 from the patient, leaving the guide wire and femoral access introducer sheath in place.

6. Completion of the Procedure

The instructions for use 58 may next include the completion of the procedure. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include:

(i) performing post-implant aortic angiography to evaluate the implantation.

(ii) checking for endovascular leaks around the endovascular graft assembly. If a leak is observed, standard endovascular techniques can be used to resolve. Additional staples may be placed, in the manner described

above.

(iii) checking for proper location, blood flow, and patency of the endovascular graft assembly.

(iv) removing the guide wires and femoral access sheaths and close the femoral arteriotomies according to standard practice (Fig. 12P).

It is to be appreciated that the general steps just described do not necessarily need to follow the order in which they were described. It is also to be appreciated that fasteners may be applied to the lumen extensions as well to connect the lumen extensions to the iliac arteries.

It will also be appreciated that the components and/or features of the preferred embodiments described herein may be used together or separately, while the depicted methods and devices may be combined or modified in whole or in part. It is contemplated that the components of the guiding device, fastener device, and helical fastener may be alternately oriented relative to each other, for example, offset, bi-axial, etc. Further, it will be understood that the various embodiments may be used in additional procedures not described herein, such as vascular trauma, arterial dissections, artificial heart valve attachment and attachment of other prosthetic device within the vascular system and generally within the body.

The foregoing is considered as illustrative only of the principles of the invention. Furthermore, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

The desired embodiments of the invention are

described above in detail for the purpose of setting forth a complete disclosure and for the sake of explanation and clarity. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

I/We Claim:

1. A system comprising

a guide defining an access path into a vessel or hollow body organ and including a distal region having a terminus, and

a fastener applier comprising a catheter sized and configured for introduction along the access path and including an actuated member that is selectively operable to generate an implantation force to implant within tissue at least one fastener, the catheter including indicia visible to a naked eye to mark when the actuated member rests at a desired distance along the access path short of the terminus of the distal region and is therefore out of contact with tissue.

2. A system according to claim 1

wherein the guide includes a passage that defines the access path, and

wherein the catheter is sized and configured for introduction through the passage, and

wherein the indicia marks when the actuated member rests at a desired distance inset within the passage from terminus of the distal region.

3. A system according to claim 2

wherein the passage comprises an interior lumen.

4. A system according to claim 1

wherein the access path includes a proximal region having a visible entry to receive the catheter, and

wherein the indicia includes a visible marking on the catheter that visibly registers with the entry of the proximal region when the actuated member rests at the desired distance short of the terminus of the distal region.

5. A system according to claim 1

wherein the distal region is deflectable.

6. A system according to claim 1

wherein the at least one fastener comprises a tissue-piercing fastener.

7. A system according to claim 6

wherein the tissue-piercing fastener comprises a helical fastener.

8. A system comprising

a guide defining an access path into a vessel or hollow body organ and including a distal region having a terminus,

a fastener applier comprising a catheter sized and configured for introduction along the access path and including an actuated member that is selectively operable to generate an implantation force to implant within tissue at least one fastener, the catheter including indicia visible to a naked eye to mark when the actuated member rests at a desired distance along the access path short of the terminus of the distal region and out of contact with tissue, and

instructions for using the guide and fastener applier comprising introducing the guide to a location at a target site within a vessel or hollow body organ where a diseased or damaged section exists, establishing the access path to a desired fastening site at the target site by manipulating the guide to orient the terminus with respect to the desired fastening site, introducing the actuated member along the access path toward the terminus; and viewing the indicia with a naked eye to detect when the actuated member rests at a desired distance along the access path short of the terminus of the distal region.

9. A method comprising

(i) providing a system as defined in claim 1 or 8

(ii) introducing the guide to a location at a target site within a vessel or hollow body organ where a diseased or damaged section exists;

(iii) establishing the access path to a desired fastening site at the target site by manipulating the guide to orient the terminus with respect to the desired fastening site;

(iv) introducing the actuated member along the access path toward the terminus; and

(v) viewing the indicia with a naked eye to detect when the actuated member rests at a desired distance along the access path short of the terminus of the distal region.

10. A method according to claim 9

(vi) after (v), advancing the actuated member to the terminus of the distal region, and

(vii) operating the actuated member to generate an implantation force to implant the into tissue at the desired fastening site.

11. A method according to claim 9

wherein (iii) includes rotating the guide and/or deflecting the distal region.

12. An apparatus comprising

a fastener applier comprising a catheter sized and configured for introduction along an access path into a vessel or hollow body organ and including an actuated member that is selectively operable in a first direction to load at least one fastener and in a second direction to generate an implantation force to implant the fastener within tissue,

an electrically powered drive member coupled to the driven member, and

a controller coupled to the drive motor including a LOAD state including means operable in response to an input command for delivering electrical current to the drive member to drive the driven member in a first direction to load a fastener onto the driven member, means for sensing electrical current delivered to the

drive member while loading the fastener onto the driven member, and means for terminating delivery of electrical current to the driven member when a prescribed amount of current is delivered to the drive member, thereby terminating the LOAD state.

13. An apparatus according to claim 12

wherein the controller includes an UNWIND state including means, operative after termination of the LOAD state, for delivering electrical current to the drive member to drive the driven member in the second direction, means for sensing a period of operation of the driven member in the second direction sufficient to reduce torque windup on the driven member during the LOAD state, means for terminating delivery of electrical current to the driven member after the period of operation, thereby terminating the UNWIND state.

14. An apparatus according to claim 13

wherein the controller includes a READY TO APPLY state including means, operative after termination of the UNWIND state, to prompt a prescribed implant fastener input command.

15. An apparatus according to claim 14

wherein the READY TO APPLY state includes means operable in response to the prescribed implant fastener input command for delivering electrical current to the drive member to drive the driven member in the second direction, means for sensing a partial period of operation of the driven member in the second direction less than a full period of operation sufficient to fully implant the fastener in tissue, means for terminating delivery of electrical current to the driven member after the partial period of operation, and means for prompting entry of either a continue implantation input command or a terminate implantation implant command.

16. An apparatus according to claim 15

wherein the READY TO APPLY STATE includes means, operative in response to the continue implantation command, for delivering electrical current to the drive member to drive the driven member in the second direction sufficient to fully implant the fastener in tissue.

17. An apparatus according to claim 15 or 16

wherein the READY TO APPLY STATE includes means, operative in response to the terminate implantation command, for delivering electrical current to the drive member to drive the driven member in the first direction sufficient to withdraw the fastener from tissue.

18. A method comprising

(i) providing the apparatus as defined in claim 12,

(ii) operating the fastener applier in the LOAD state to load a fastener onto the driven member, and

(iii) after (ii), introducing the fastener applier to a location at a target site within a vessel or hollow body organ where a diseased or damaged section exists.

19. A method comprising

(i) providing the apparatus as defined in claim 13,

(ii) operating the fastener applier in the LOAD and UNWIND states to load a fastener onto the driven member, and

(iii) after (ii), introducing the fastener applier to a location at a target site within a vessel or hollow body organ where a diseased or damaged section exists.

20. A seal assembly

a first seal component with at least one guide tube formed therein,

a second seal component with at least one guide tube formed therein, the second seal component registering with the first seal component with at least one guide tube in the second component coaxially aligned with at least one guide tube in the first component,

a septum sandwiched between the first and second

seal components, the septum accommodating passage of a control filament from one the coaxially aligned guide tubes, through the septum, to the other one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament.

21. An assembly according to claim 20 wherein at least one of the first and second seal components is substantially rigid.

22. An assembly according to claim 21 wherein the septum comprises a soft material.

23. An assembly according to claim 21 wherein the septum comprises silicone rubber.

24. An assembly according to claim 21 wherein the septum comprises a gasket.

25. An assembly according to claim 20 wherein both of the first and second seal components are substantially rigid.

26. An assembly according to claim 25 wherein the septum comprises a soft material.

27. An assembly according to claim 25 wherein the septum comprises silicone rubber.

28. An assembly according to claim 25 wherein the septum comprises a gasket.

29. An apparatus comprising

a catheter assembly including an operative element that, in use, is exposed to a body fluid,

a control element,

a control filament coupled at one end to the control element and to an opposite end to the operative element, and

a seal assembly between the control element and the operative element through which the control filament passes to prevent contact between the body fluid and the control element, the seal assembly comprising

a first seal component with at least one guide

tube formed therein,

a second seal component with at least one guide tube formed therein, the second seal component registering with the first seal component with at least one guide tube in the second component coaxially aligned with at least one guide tube in the first component, and

a septum sandwiched between the first and second seal components, the septum accommodating passage of the control filament from one the coaxially aligned guide tubes, through the septum, to the other one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament.

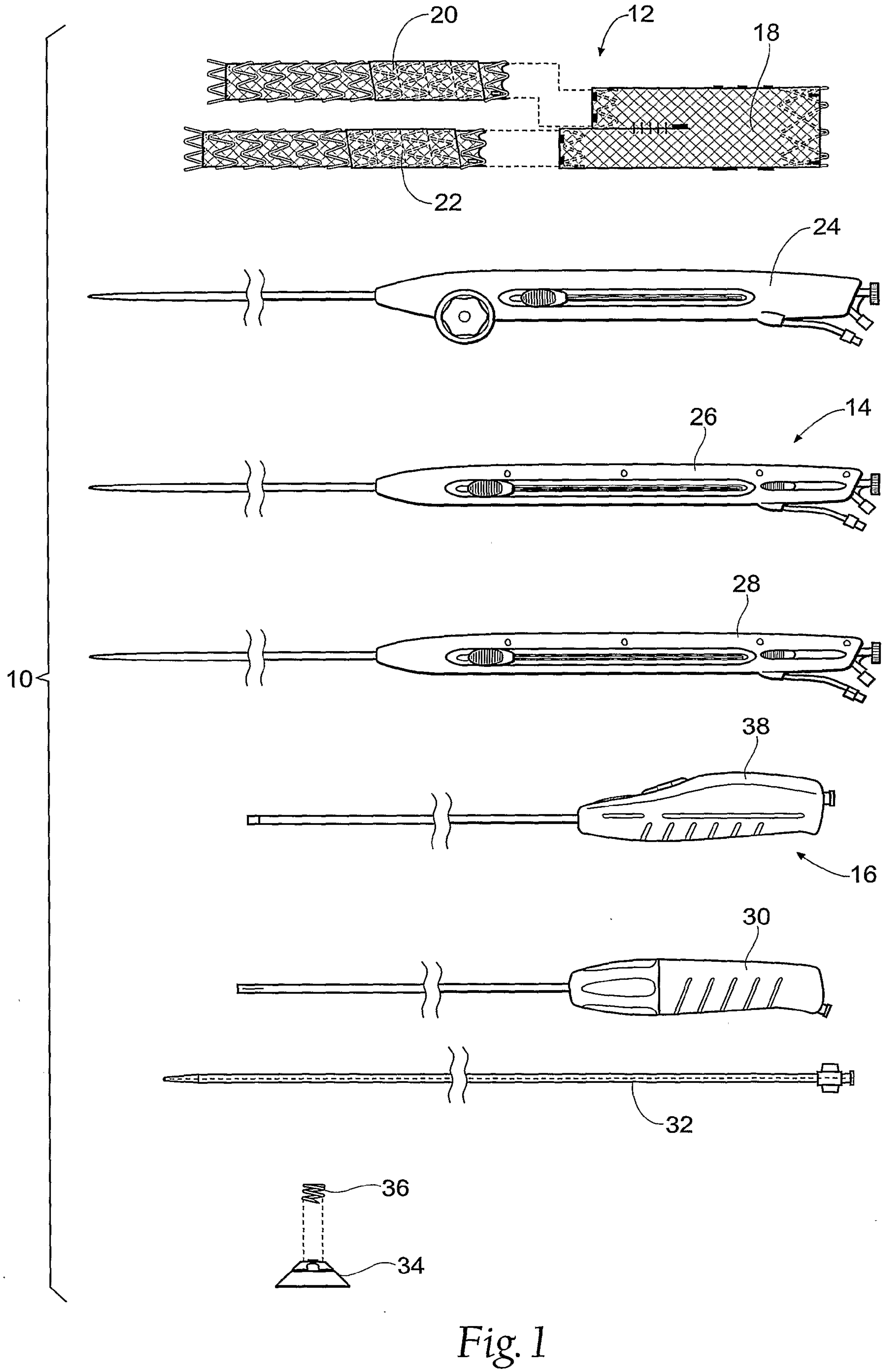
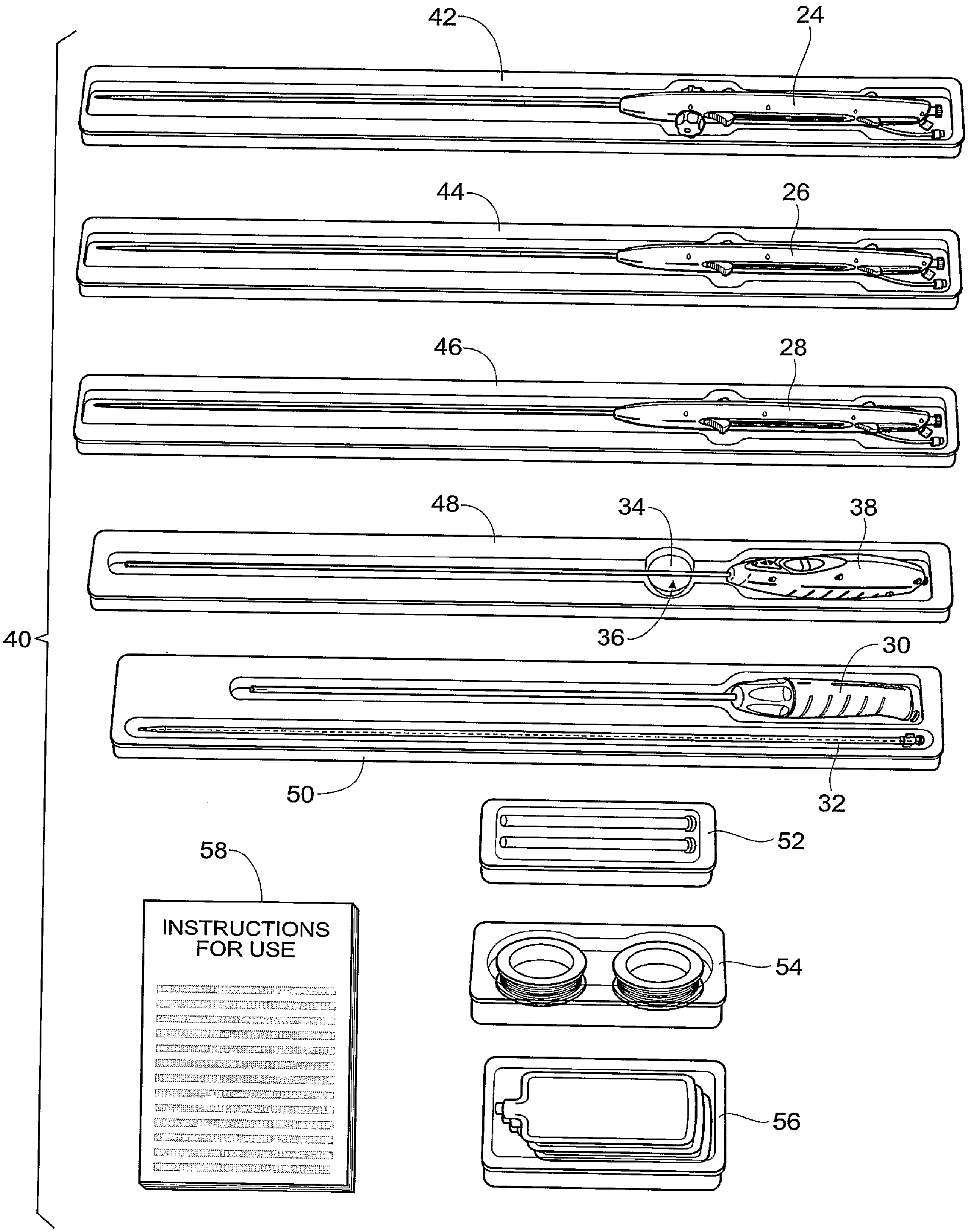


Fig. 1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INSTRUCTIONS FOR USE
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56

Fig. 2

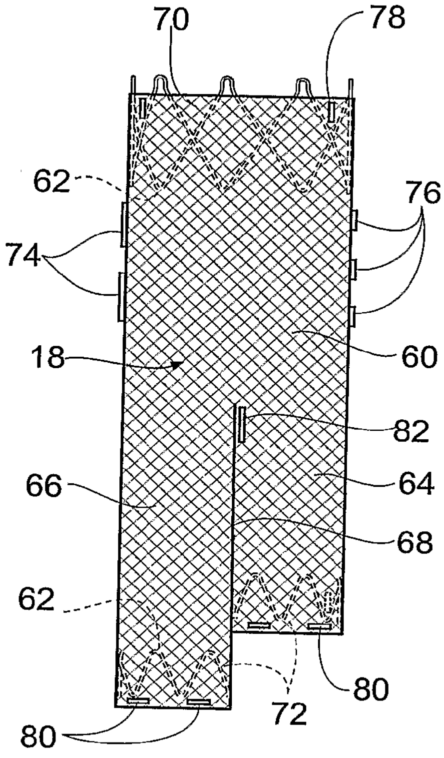


Fig. 3A

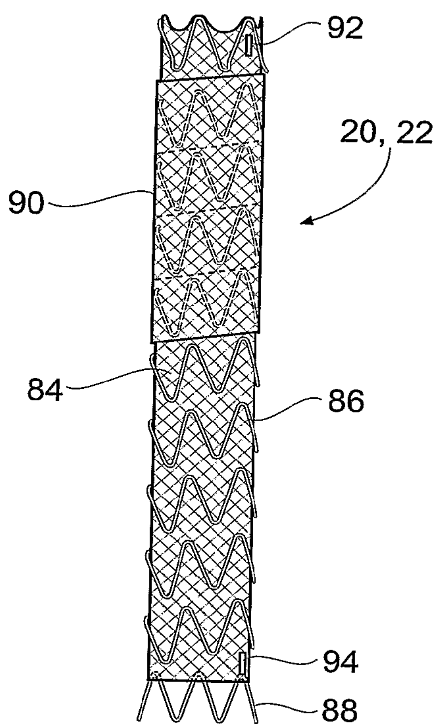


Fig. 3B

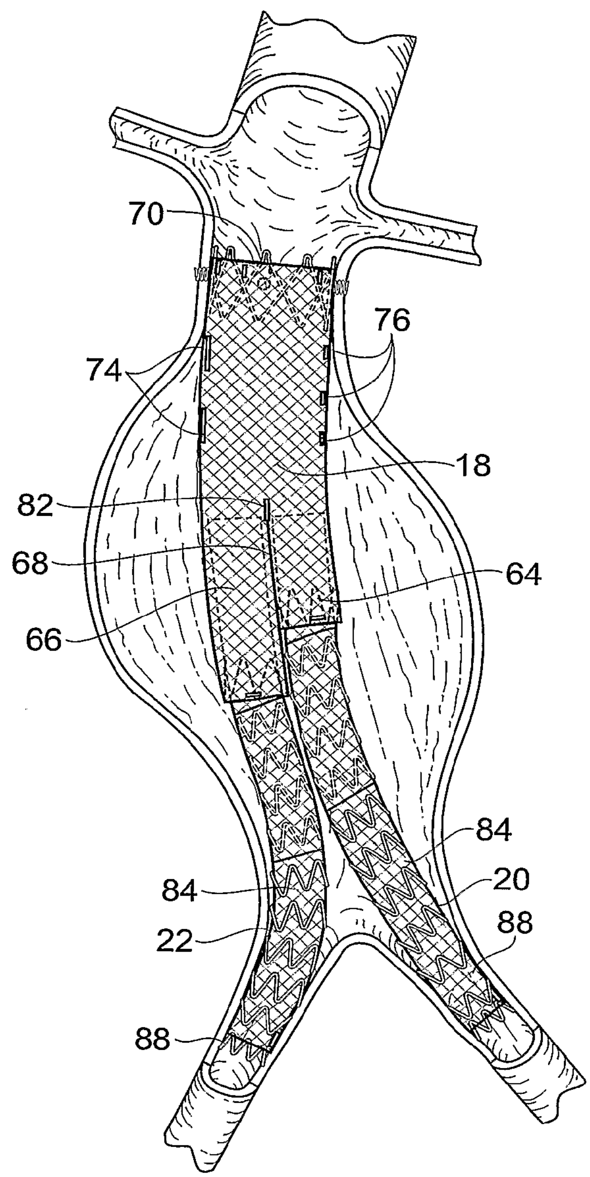


Fig. 3C

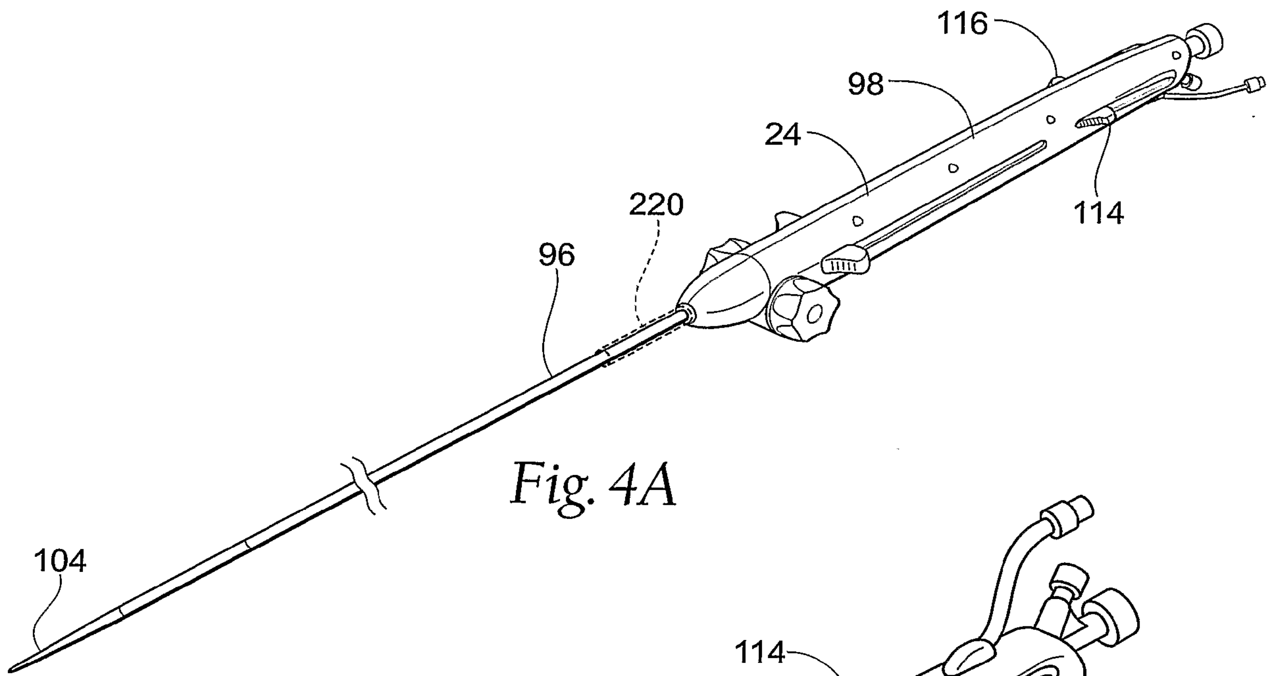


Fig. 4A

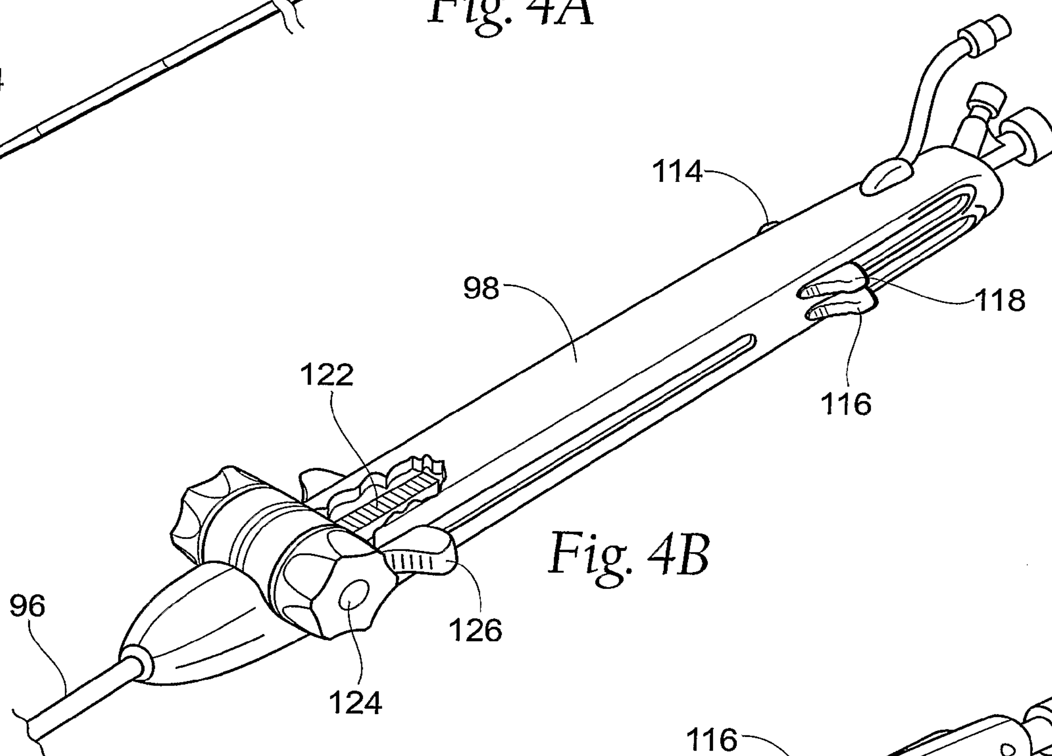


Fig. 4B

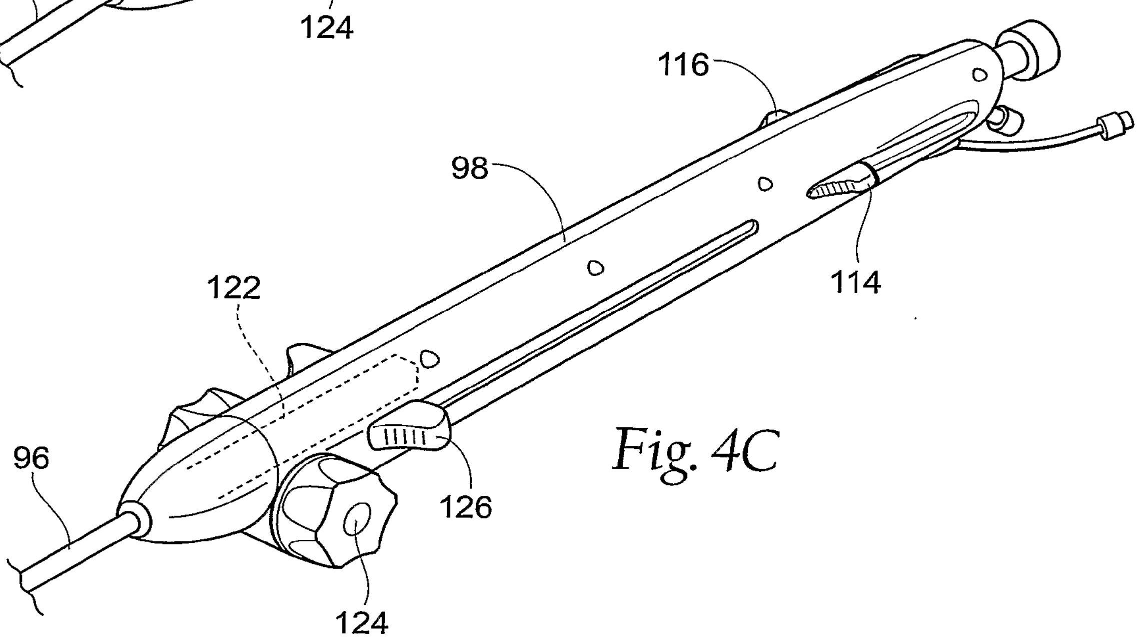
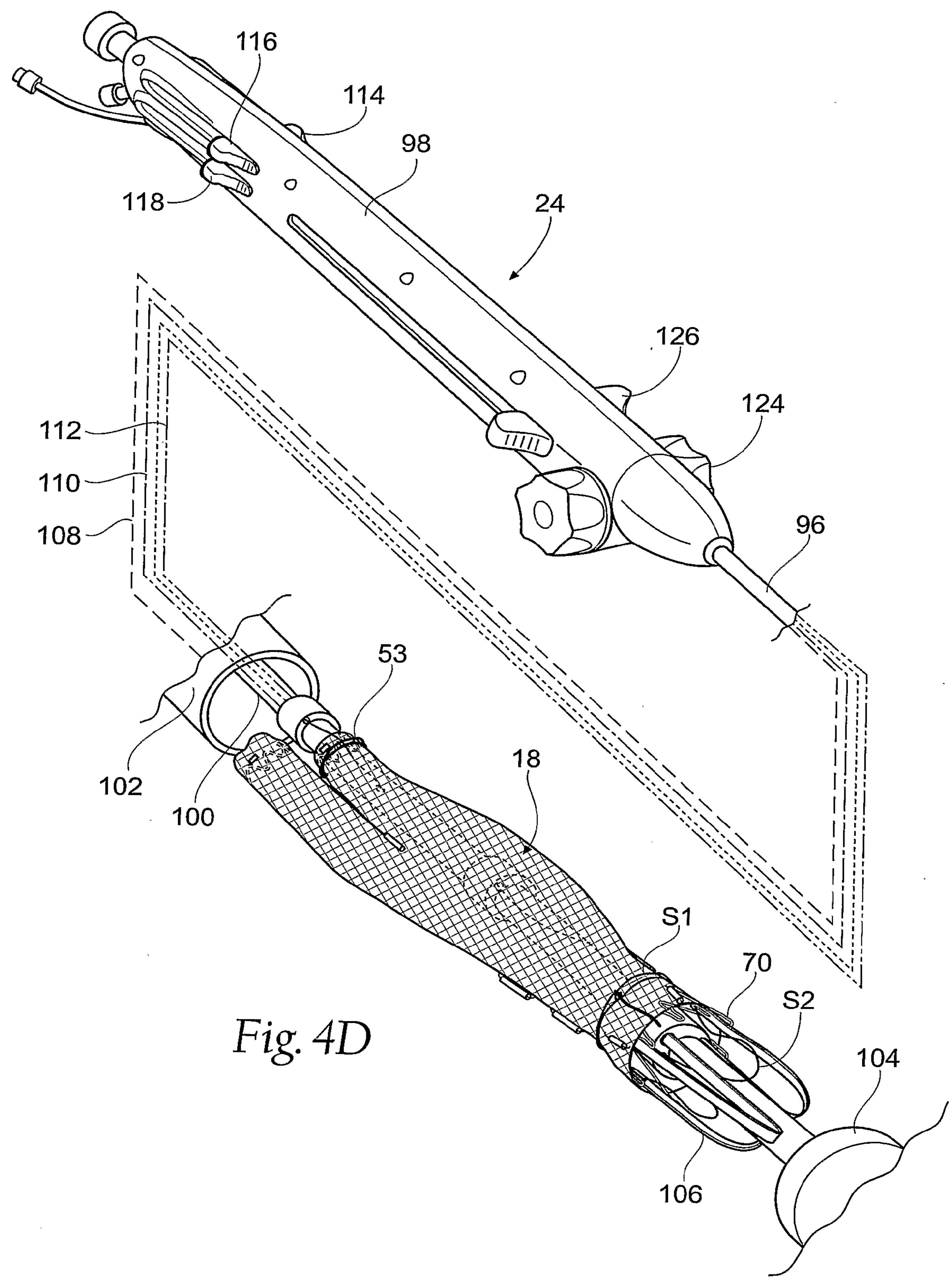


Fig. 4C


116
114
98
118
24
126
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102
100
S1
70
S2
104
106

Fig. 4D

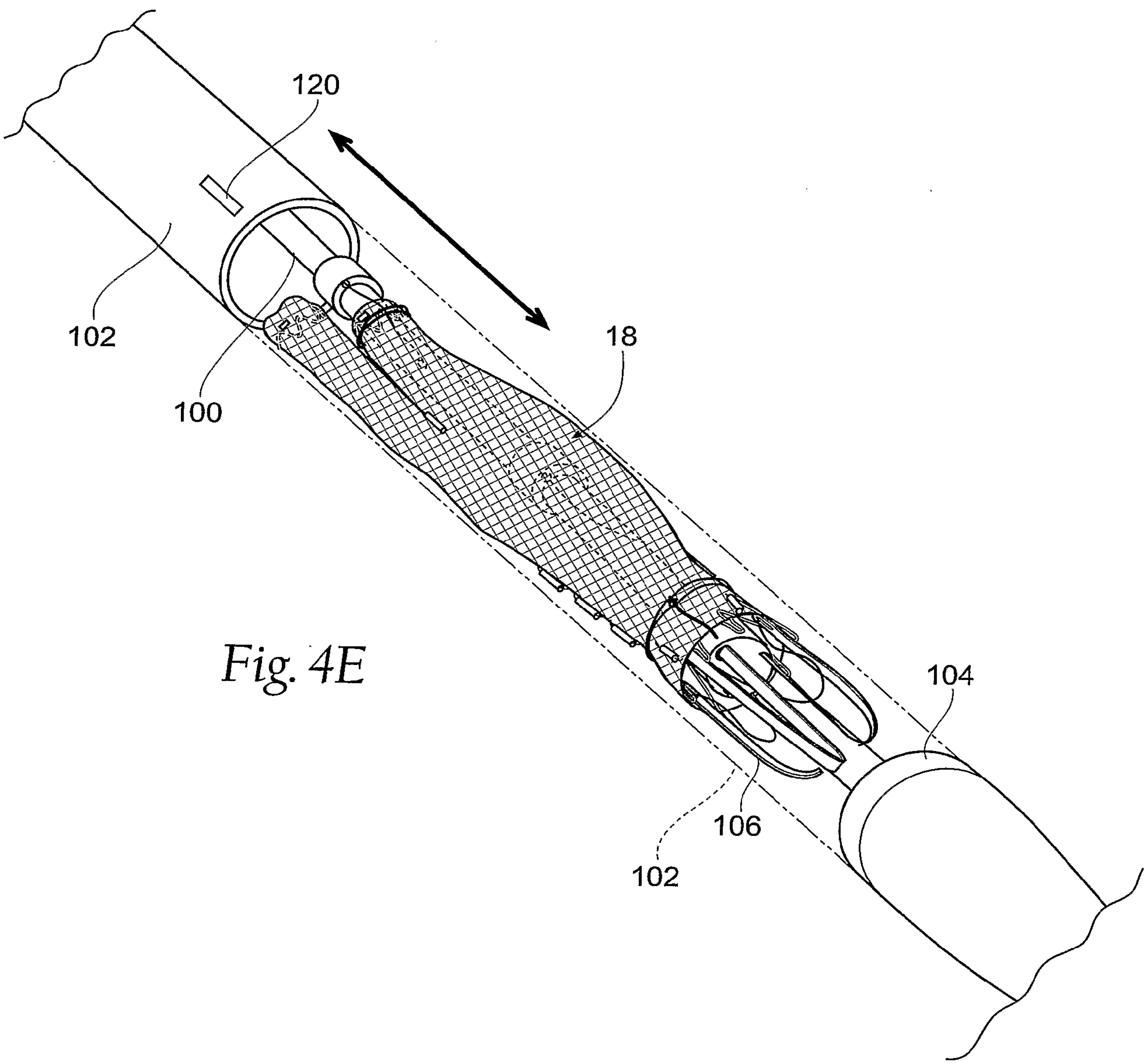


Fig. 4E

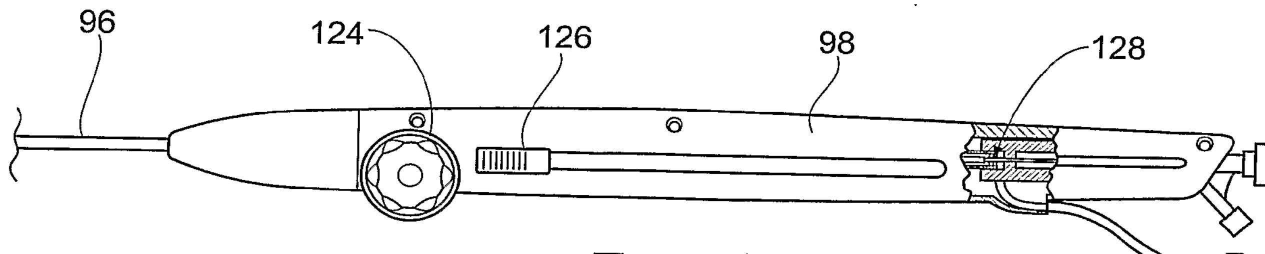


Fig. 5A

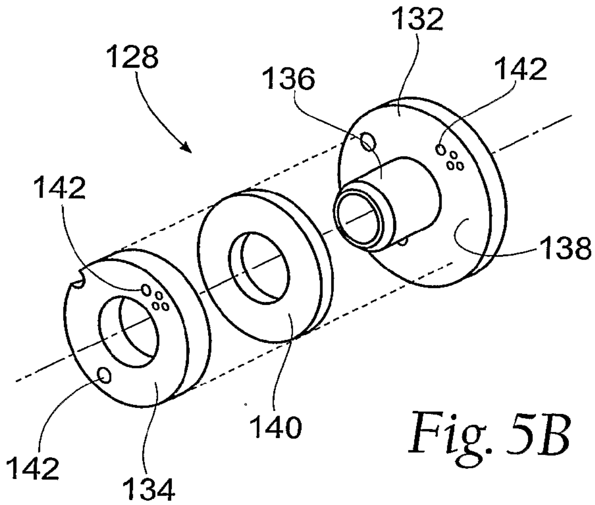


Fig. 5B

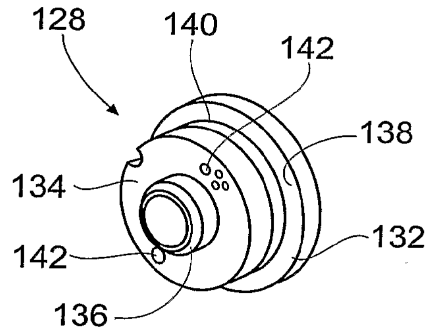


Fig. 5C

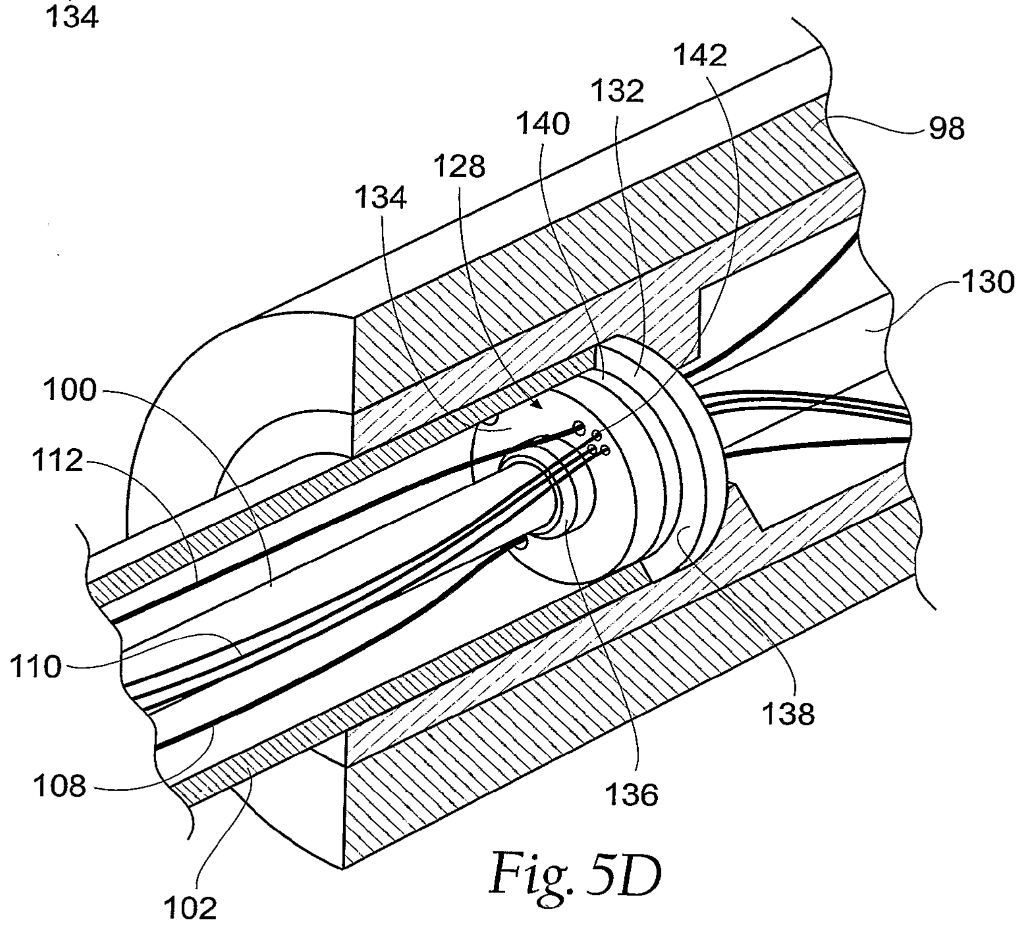


Fig. 5D

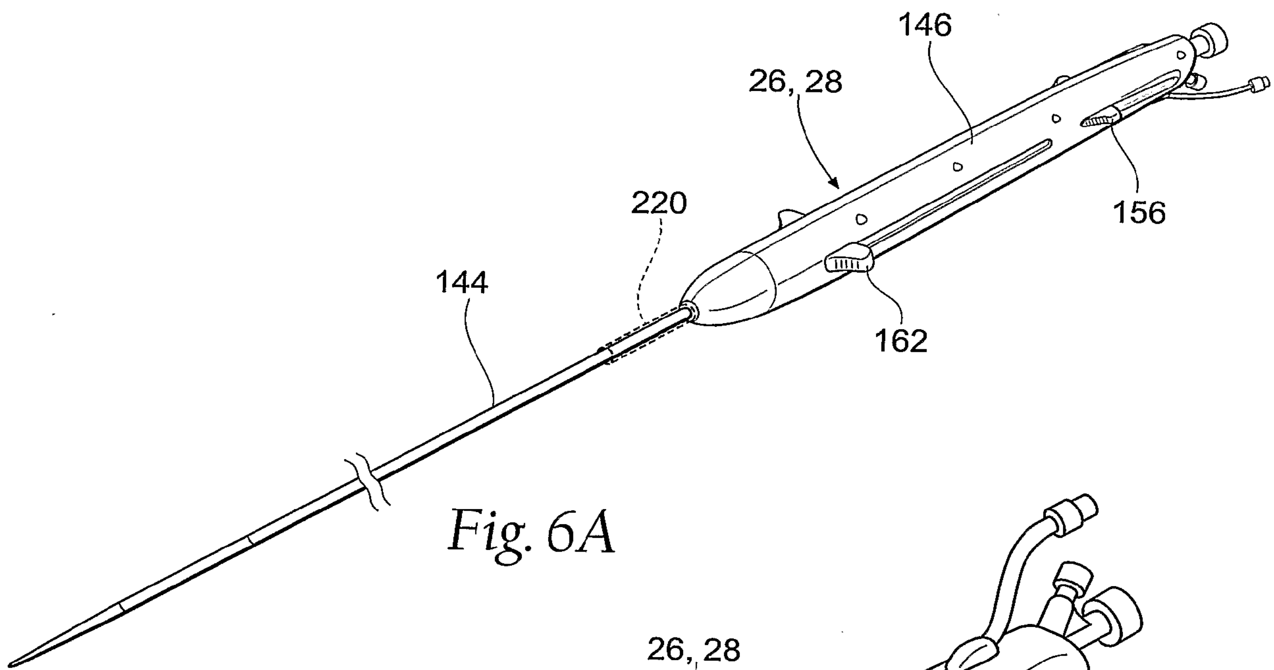


Fig. 6A

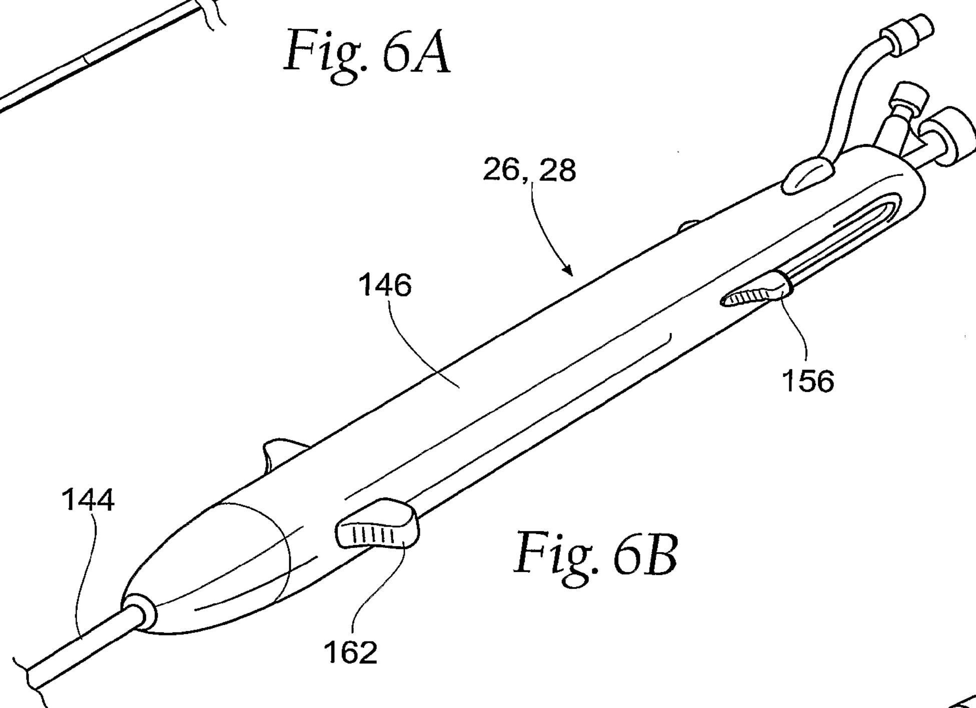


Fig. 6B

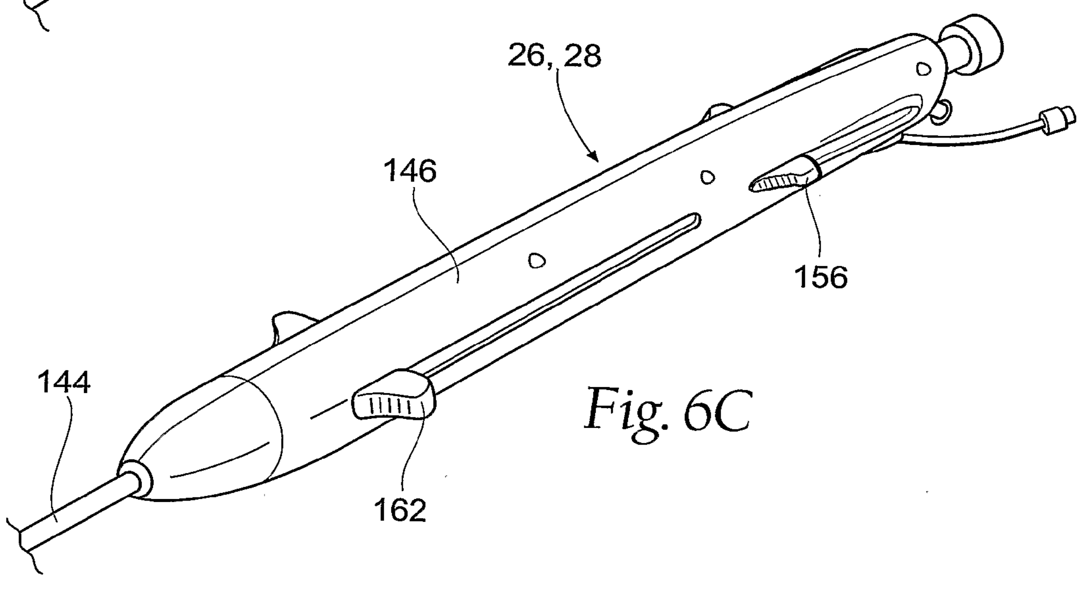


Fig. 6C

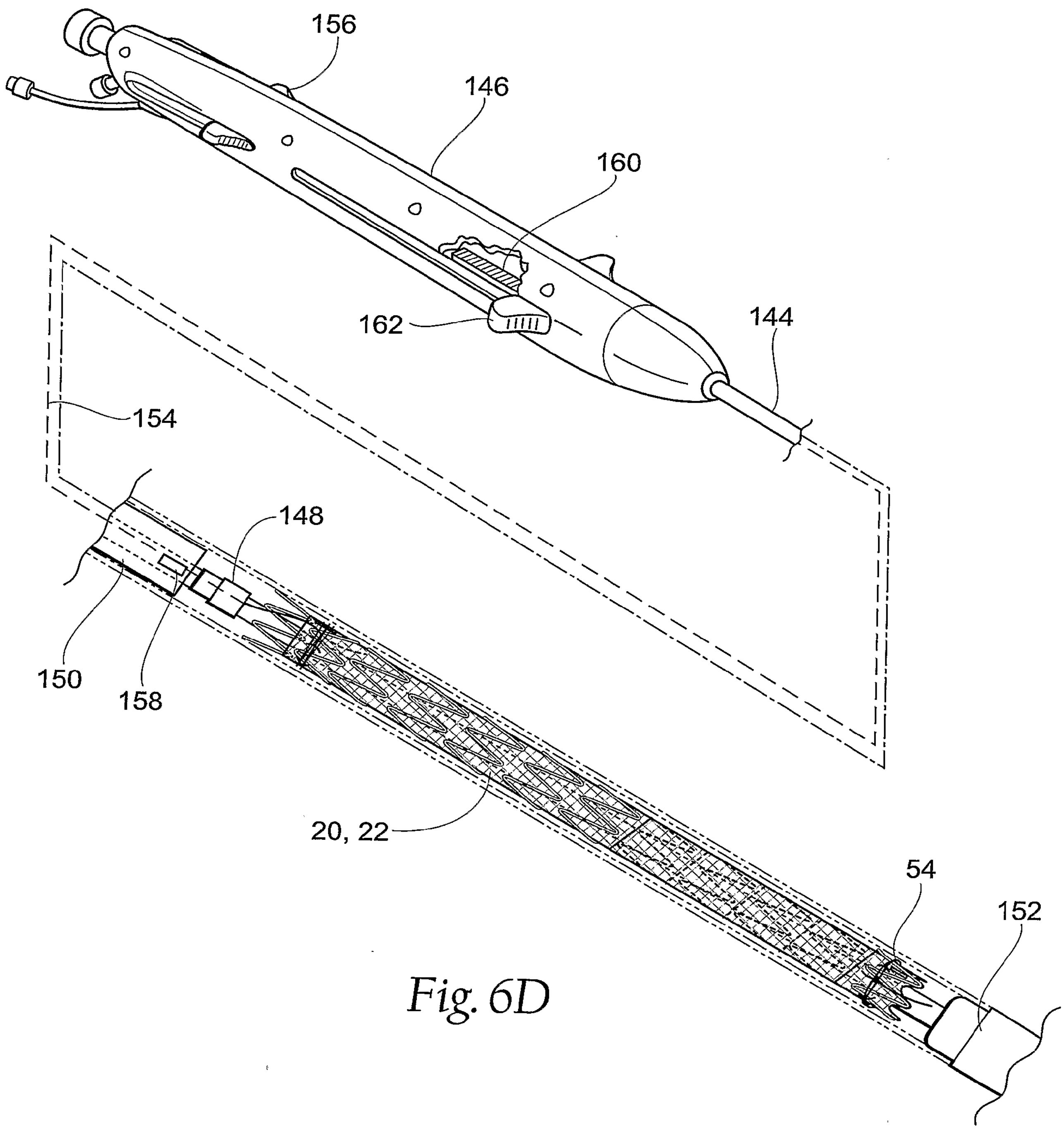


Fig. 6D

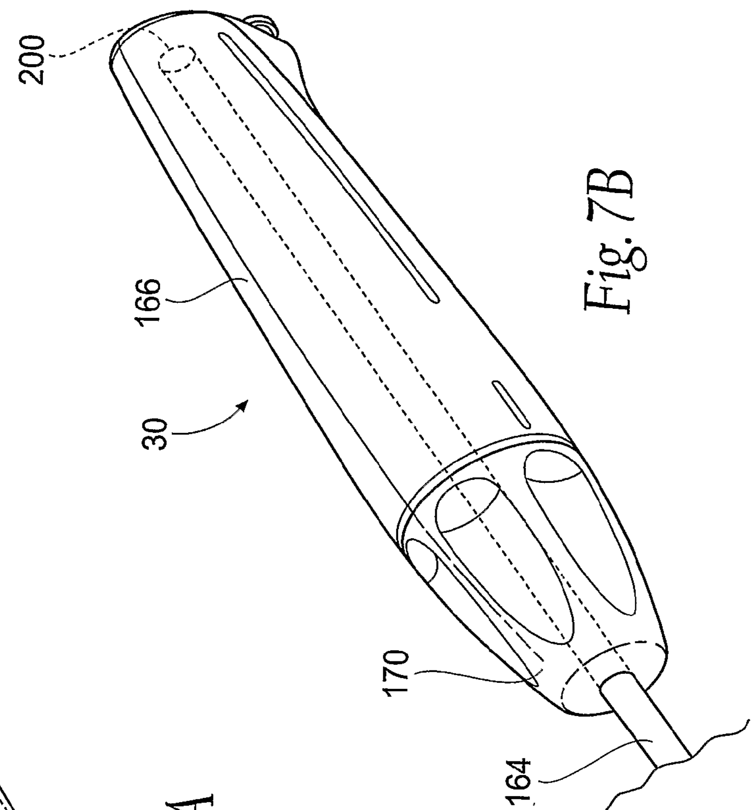


Fig. 7B

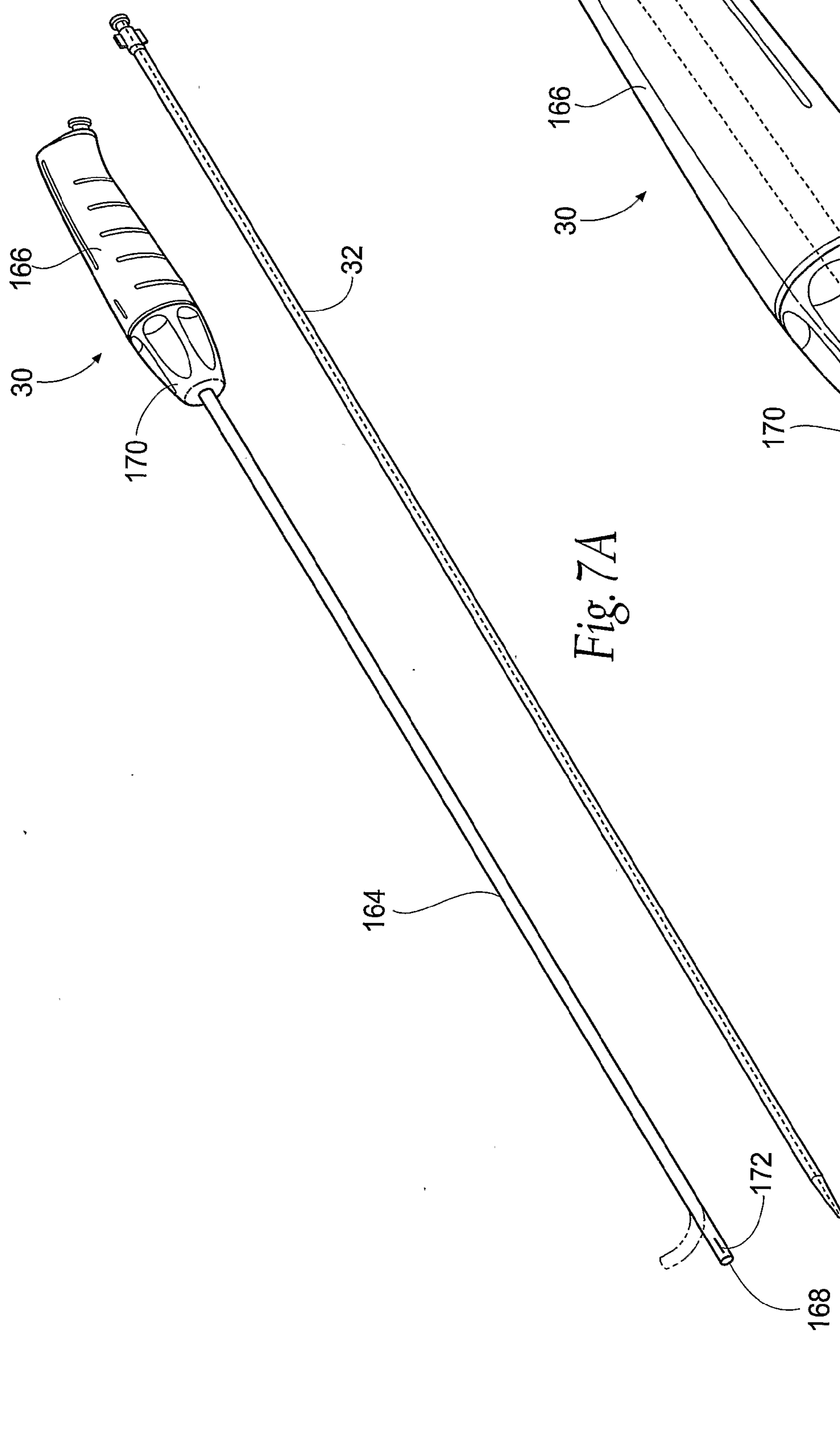


Fig. 7A

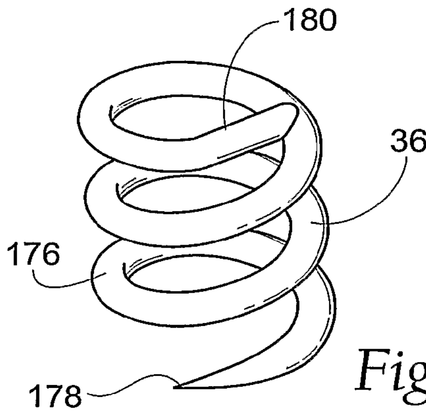


Fig. 8A

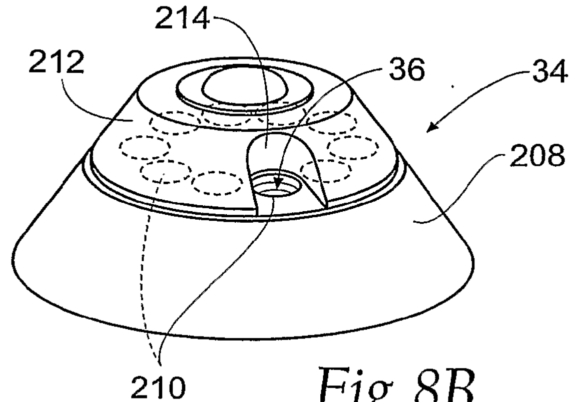


Fig. 8B

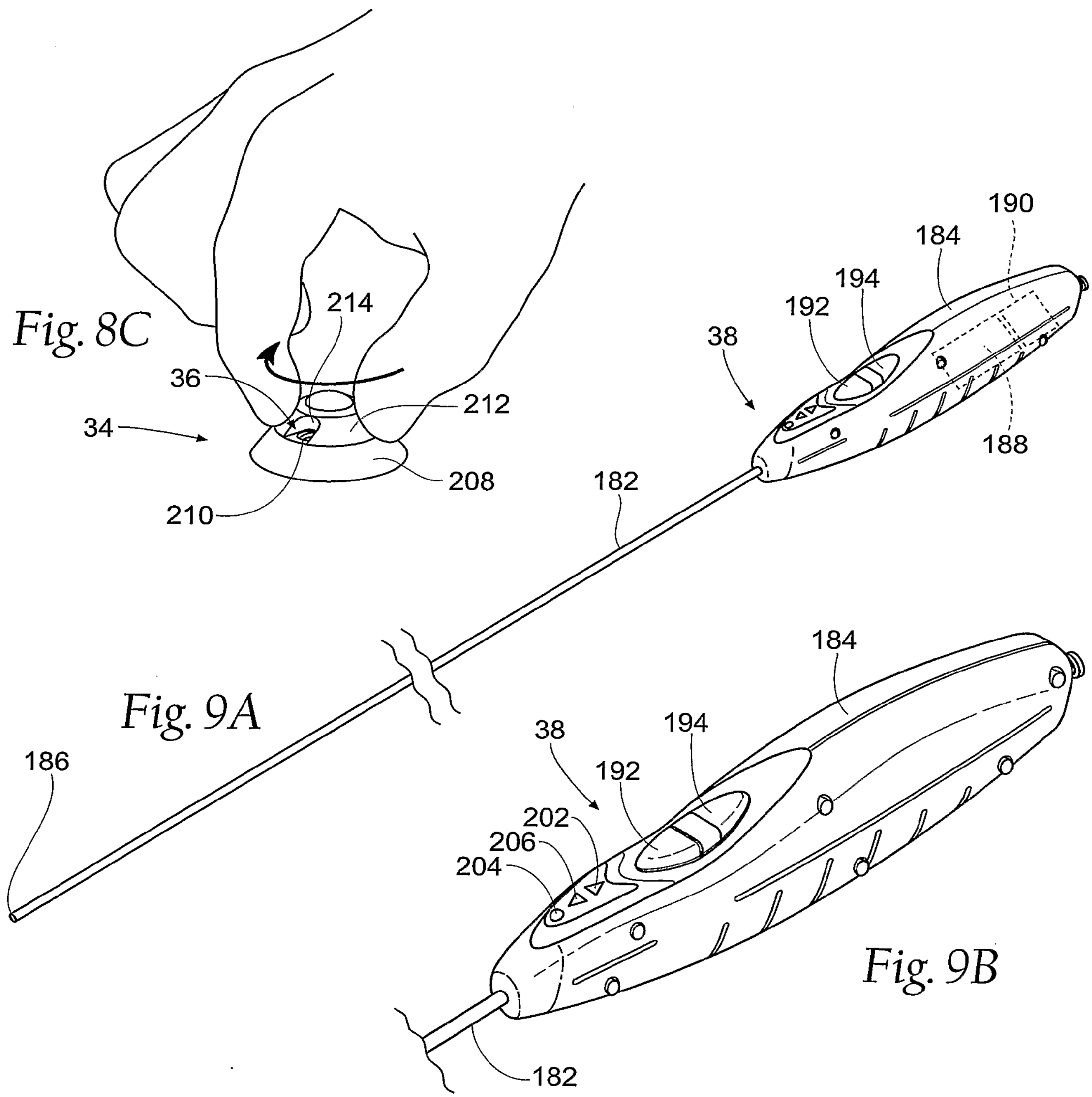


Fig. 8C

Fig. 9A

Fig. 9B

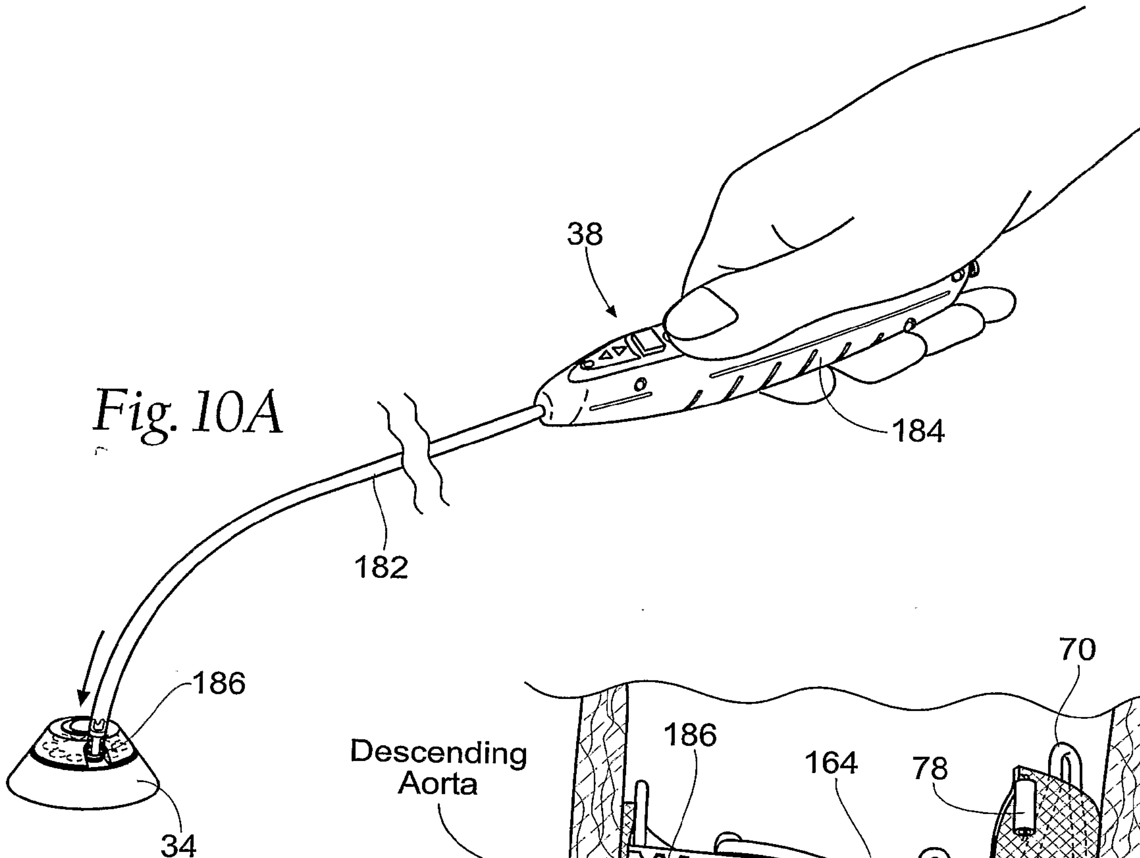


Fig. 10A

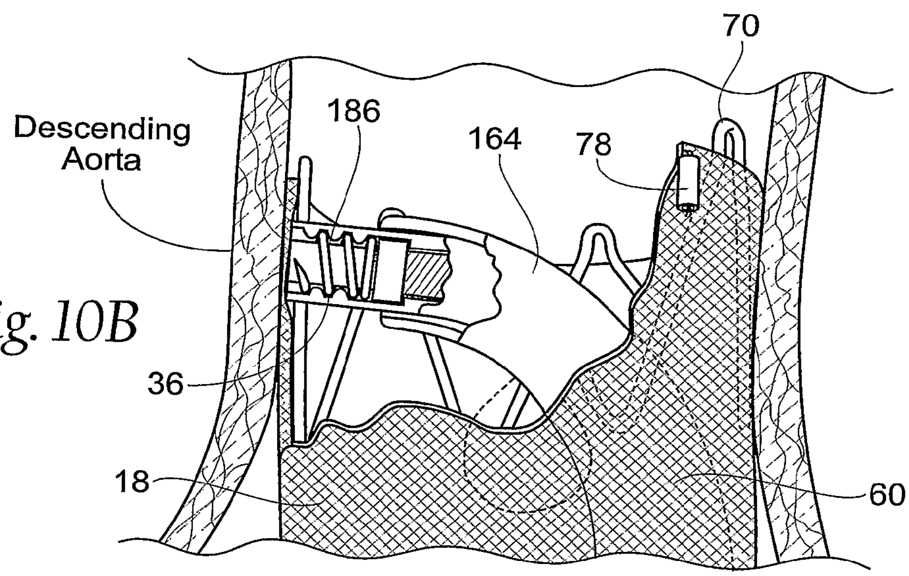


Fig. 10B

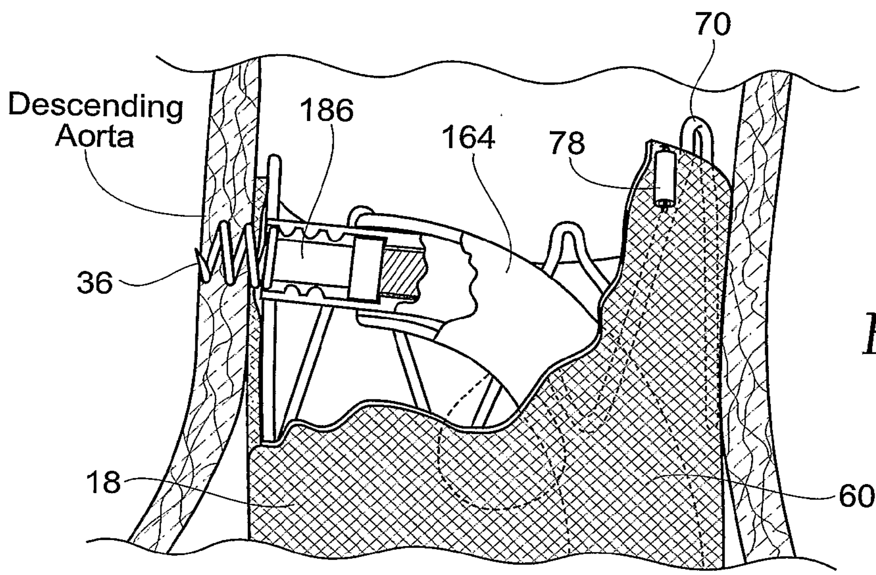
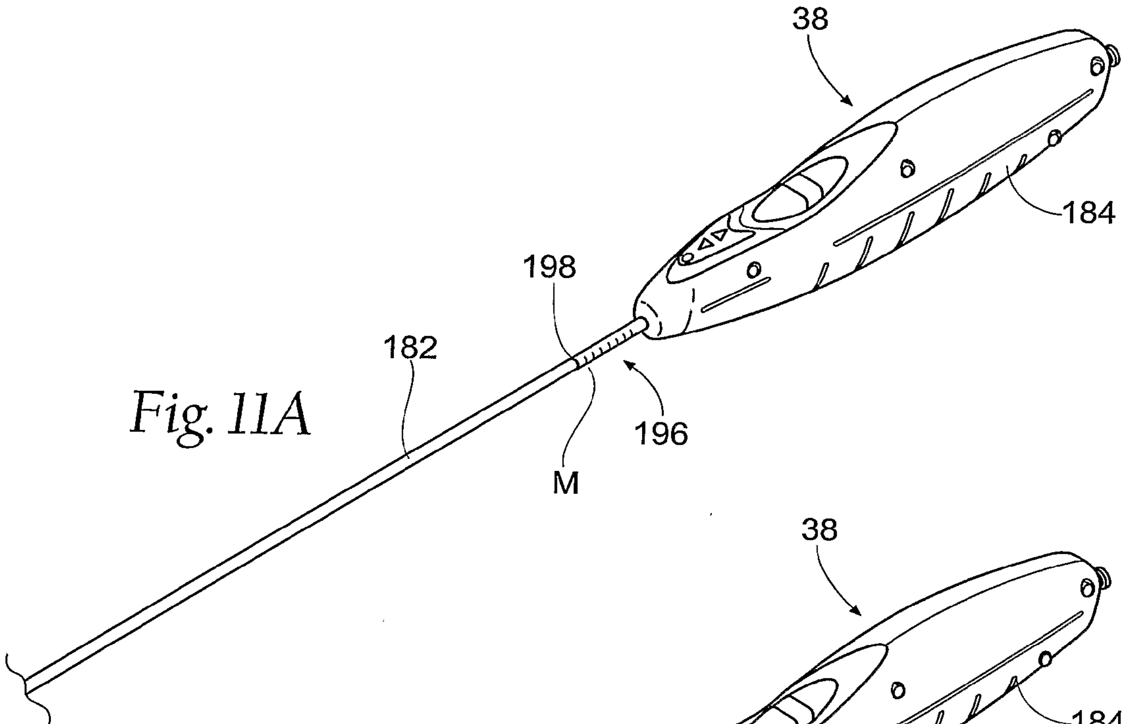


Fig. 10C



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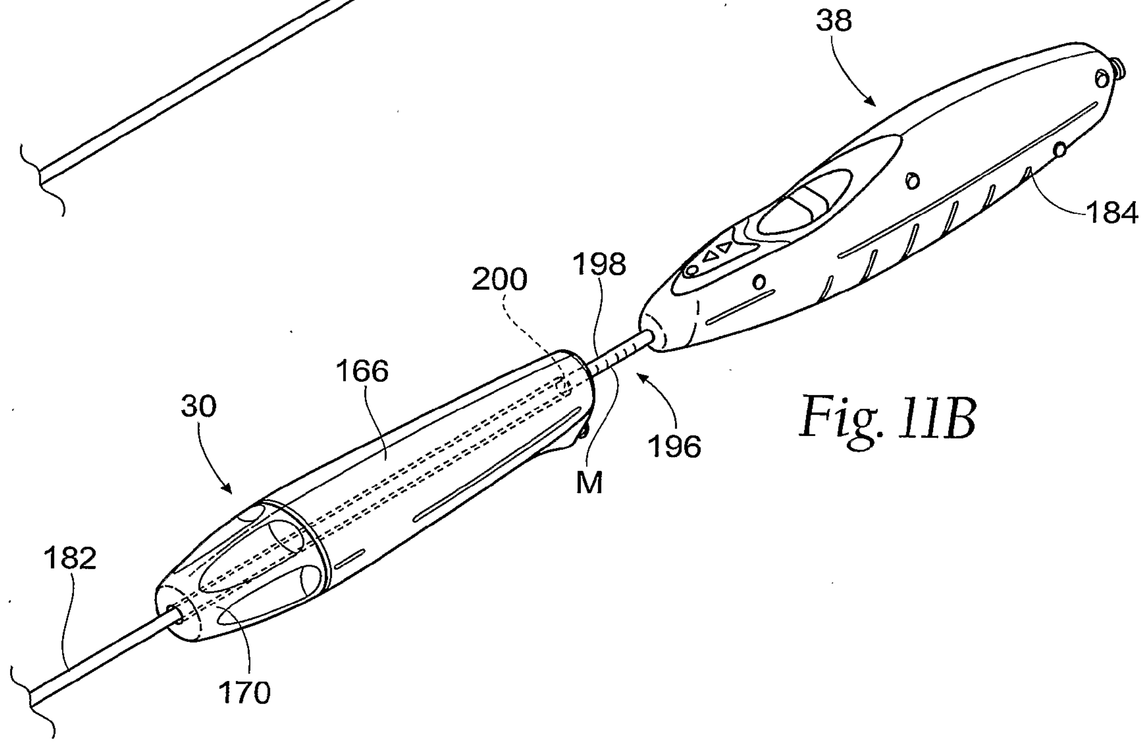


Fig. 11B

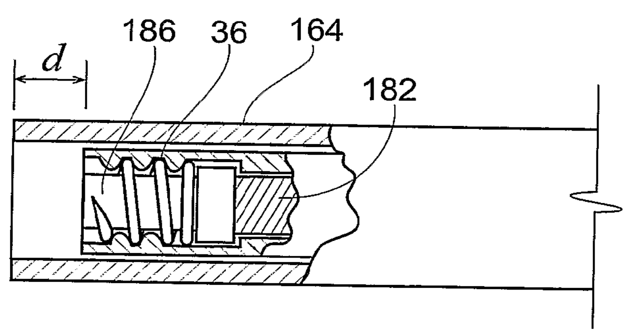


Fig. 11C

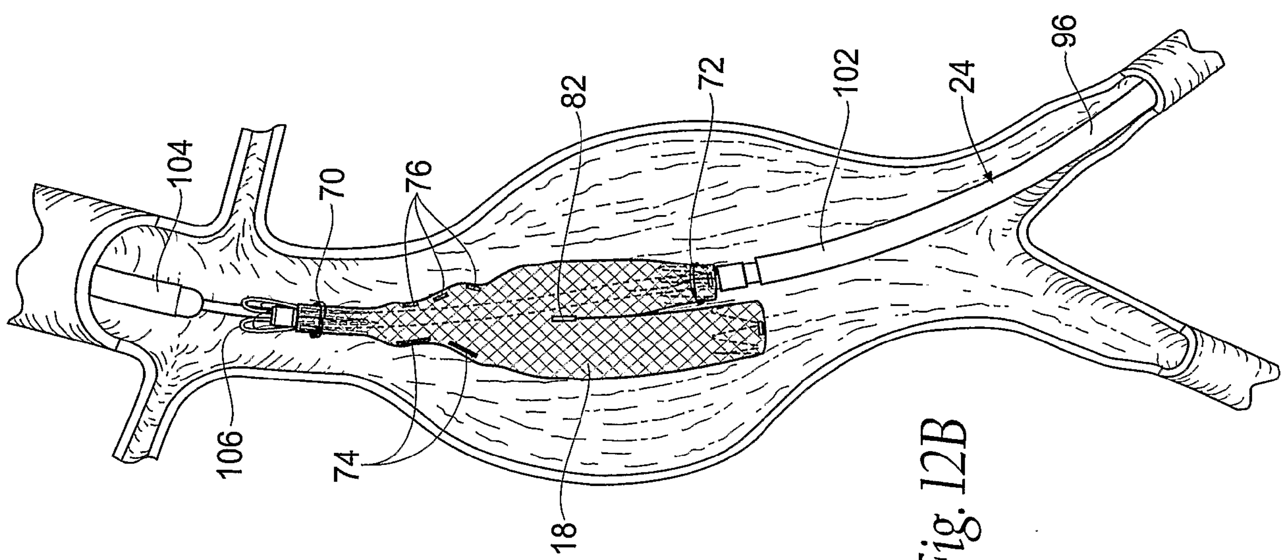


Fig. 12B

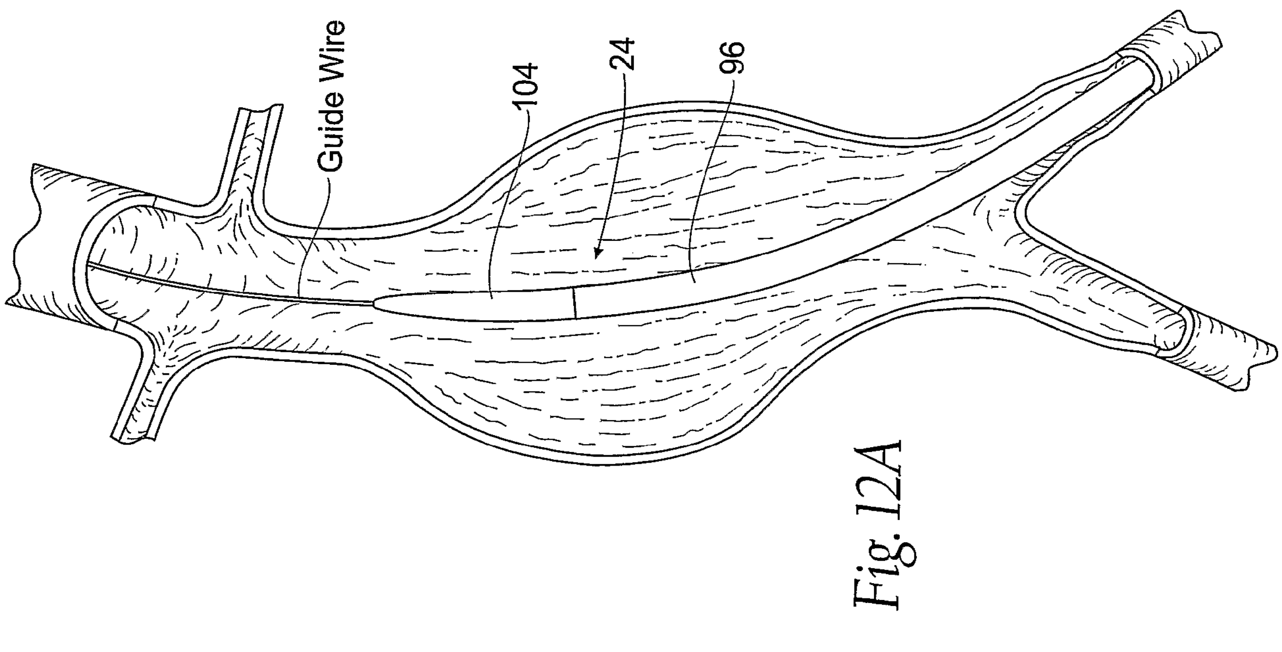


Fig. 12A

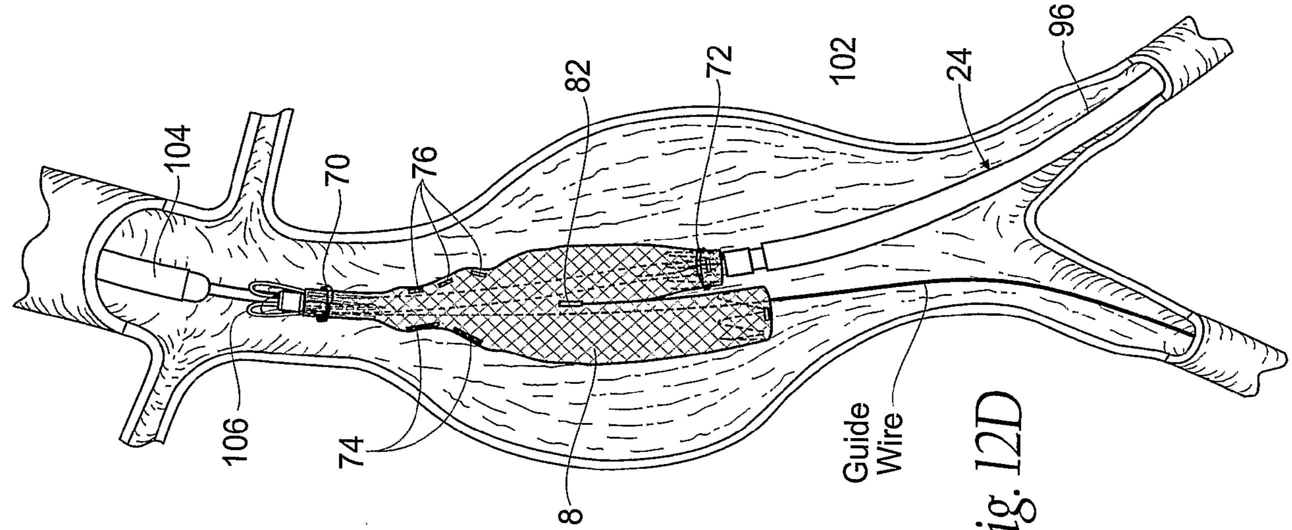


Fig. 12D

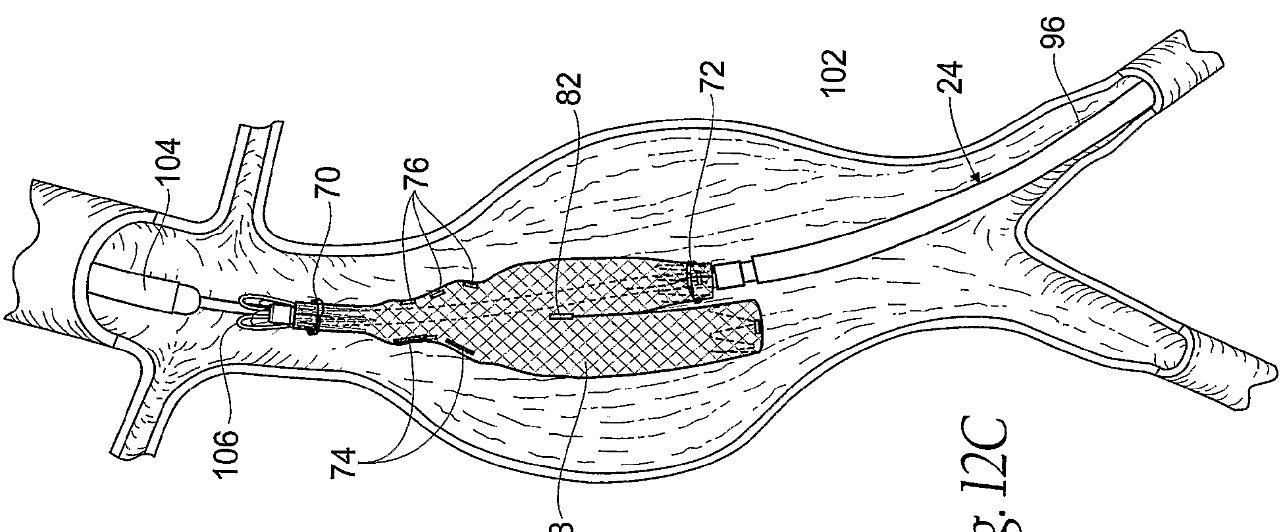


Fig. 12C

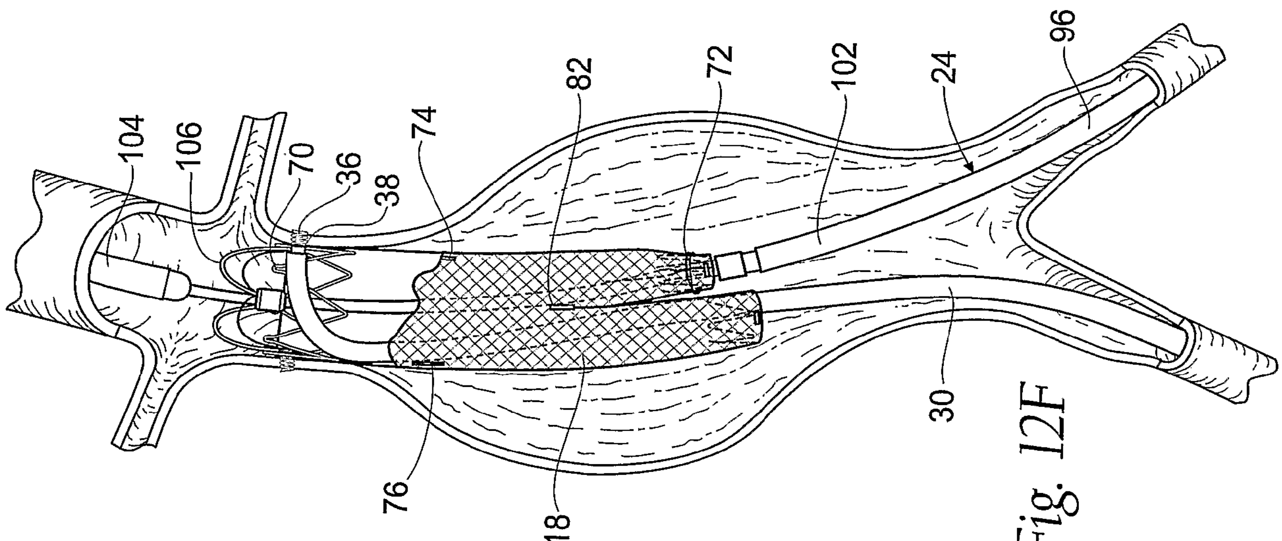


Fig. 12F

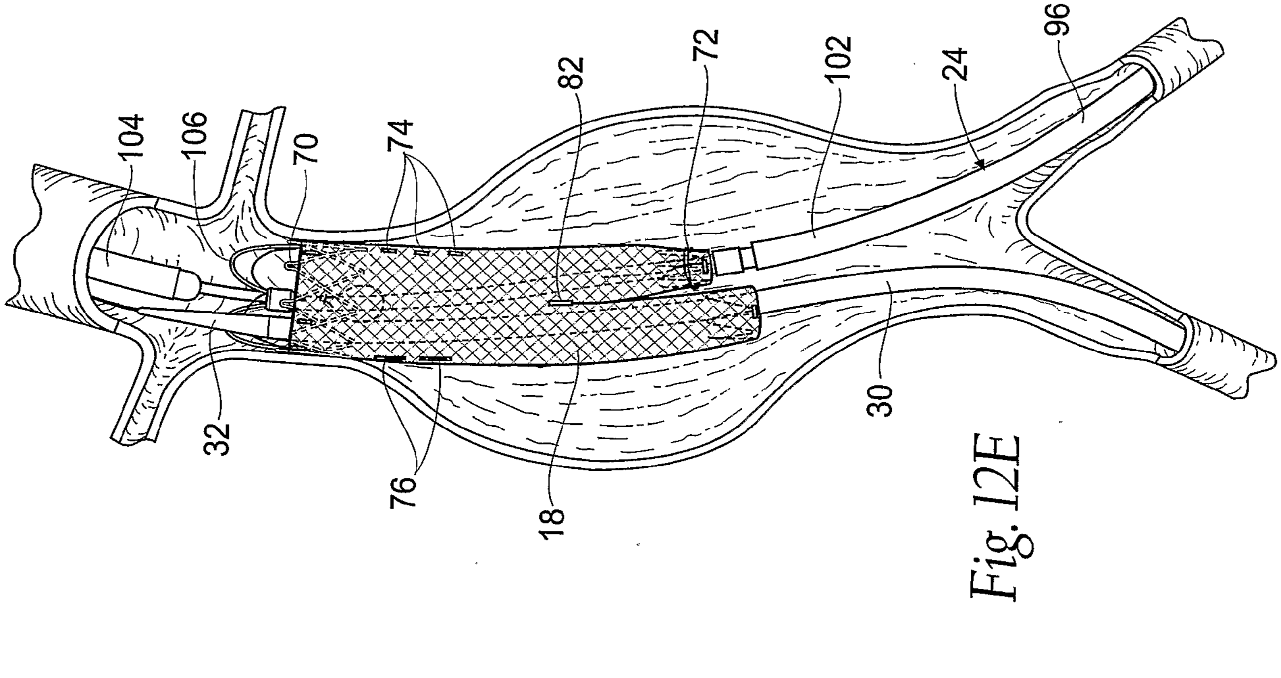


Fig. 12E

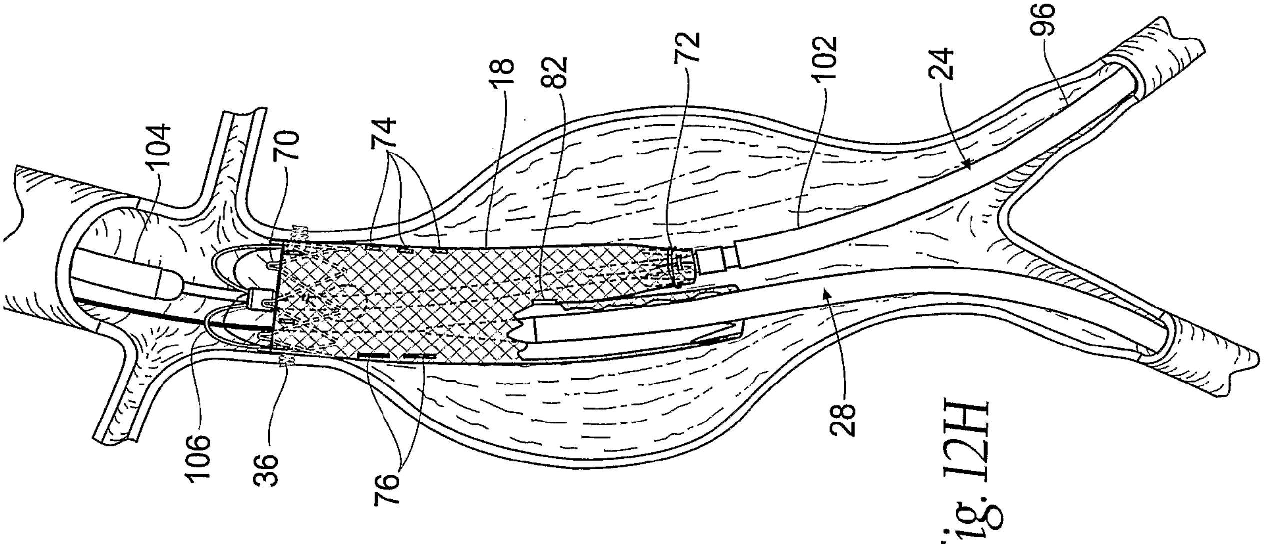


Fig. 12H

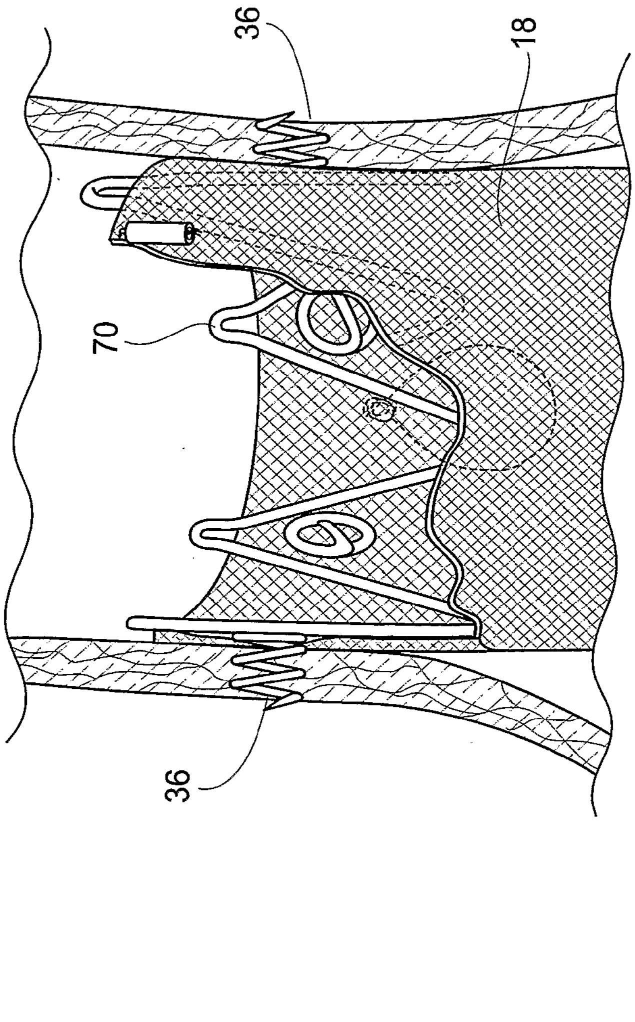


Fig. 12G

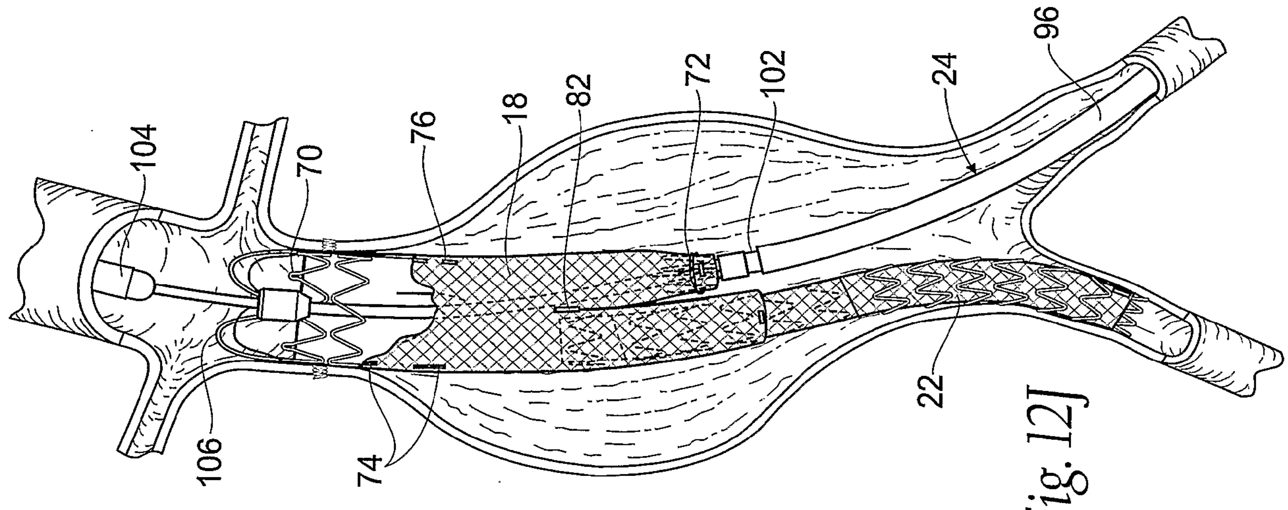


Fig. 12J

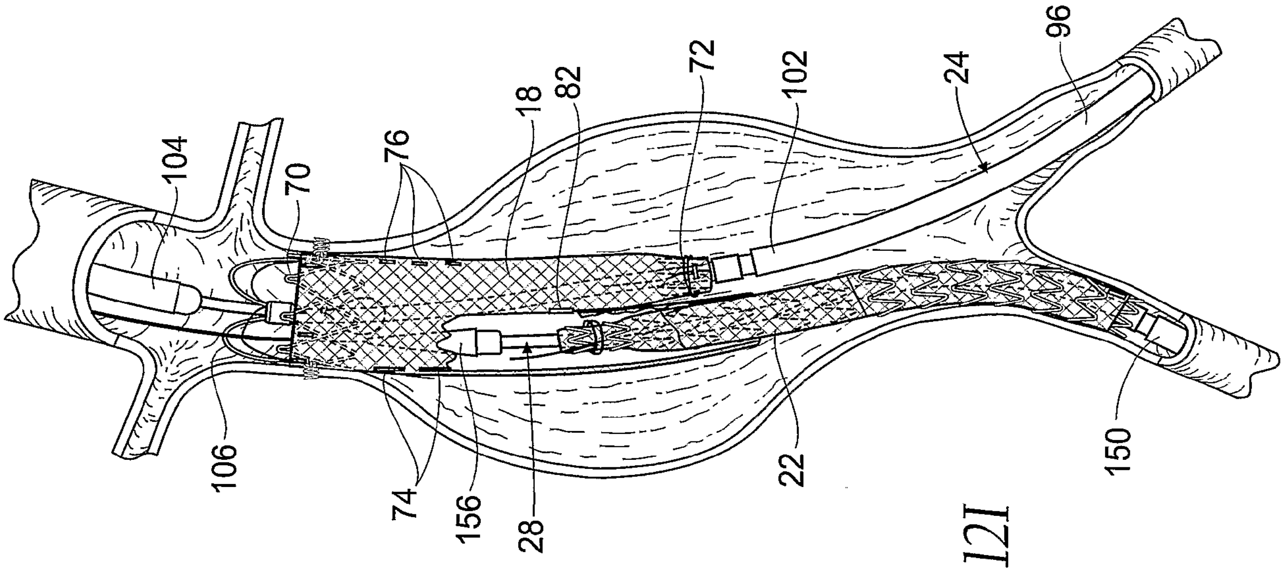


Fig. 12I

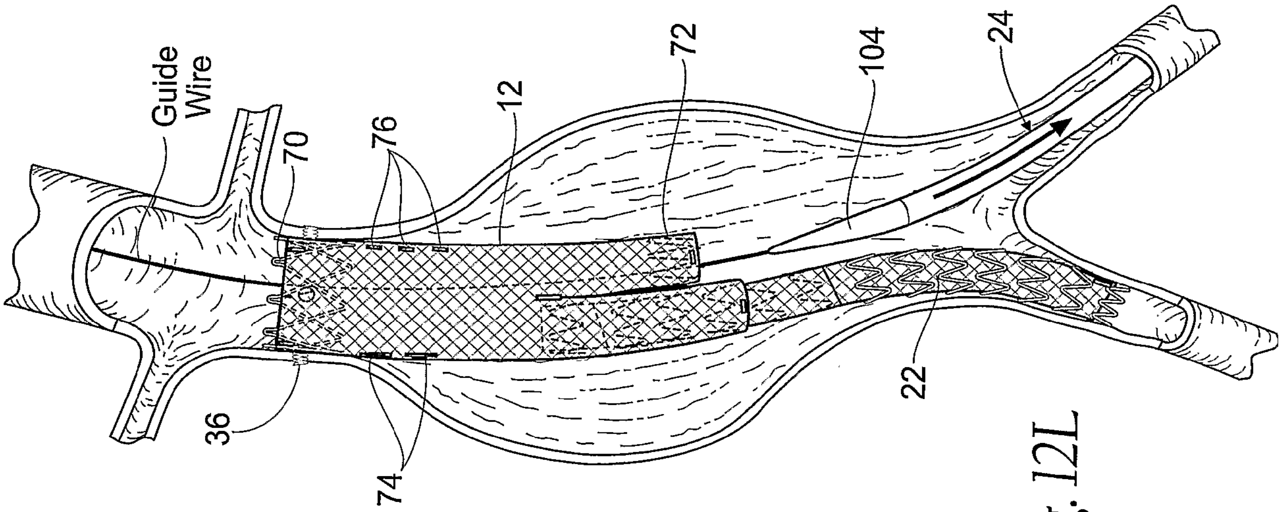


Fig. 12L

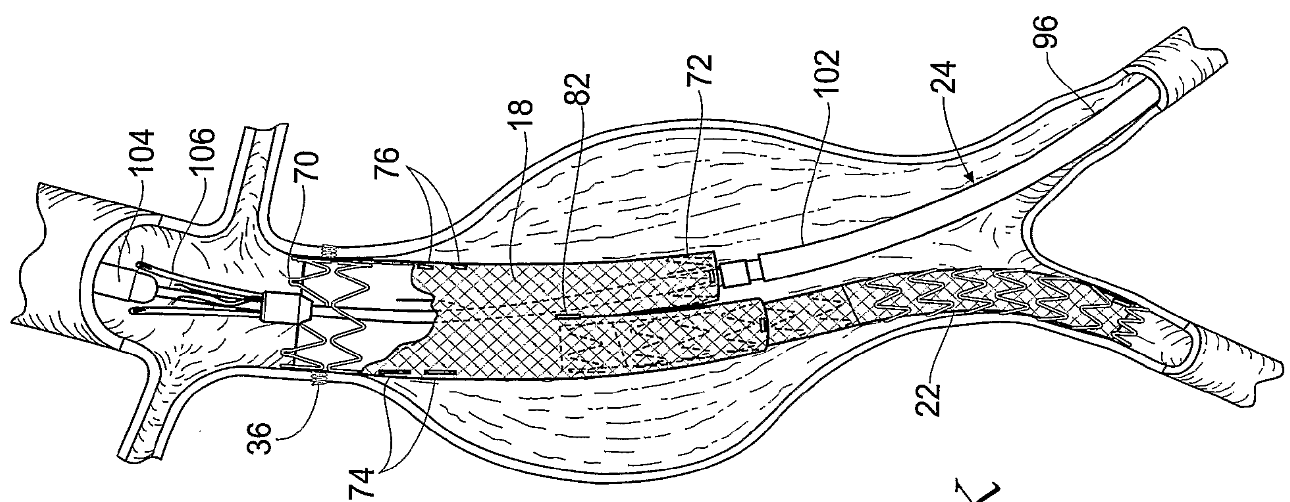


Fig. 12K

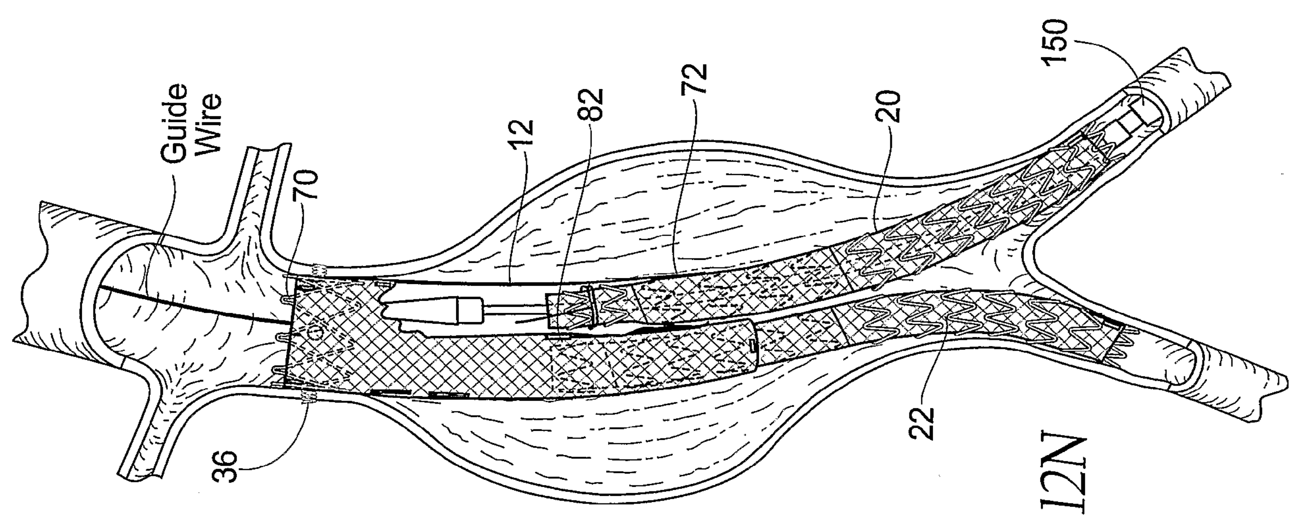


Fig. 12N

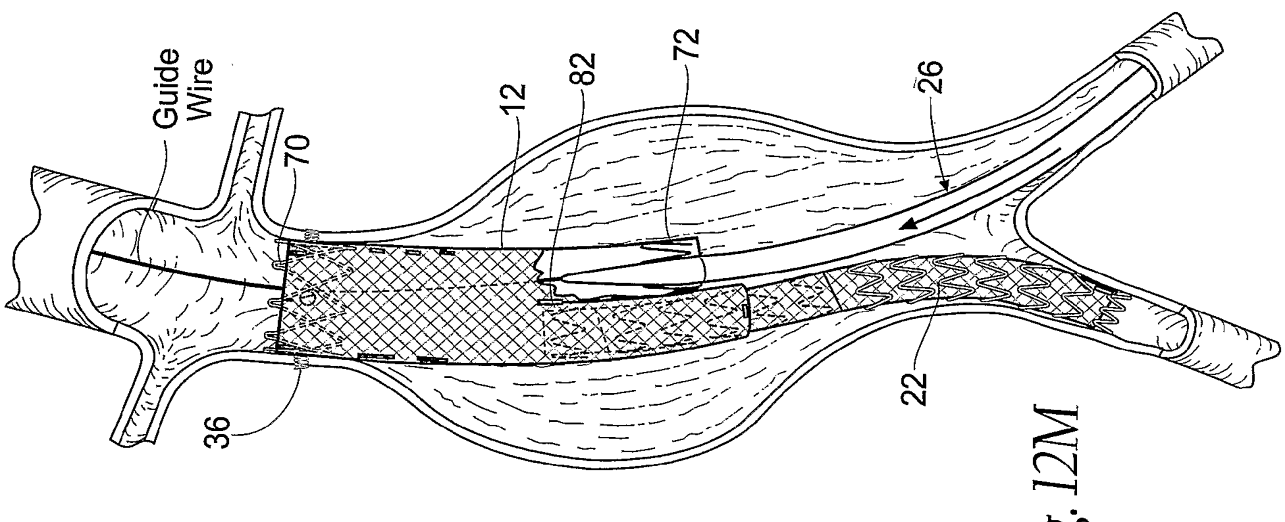


Fig. 12M

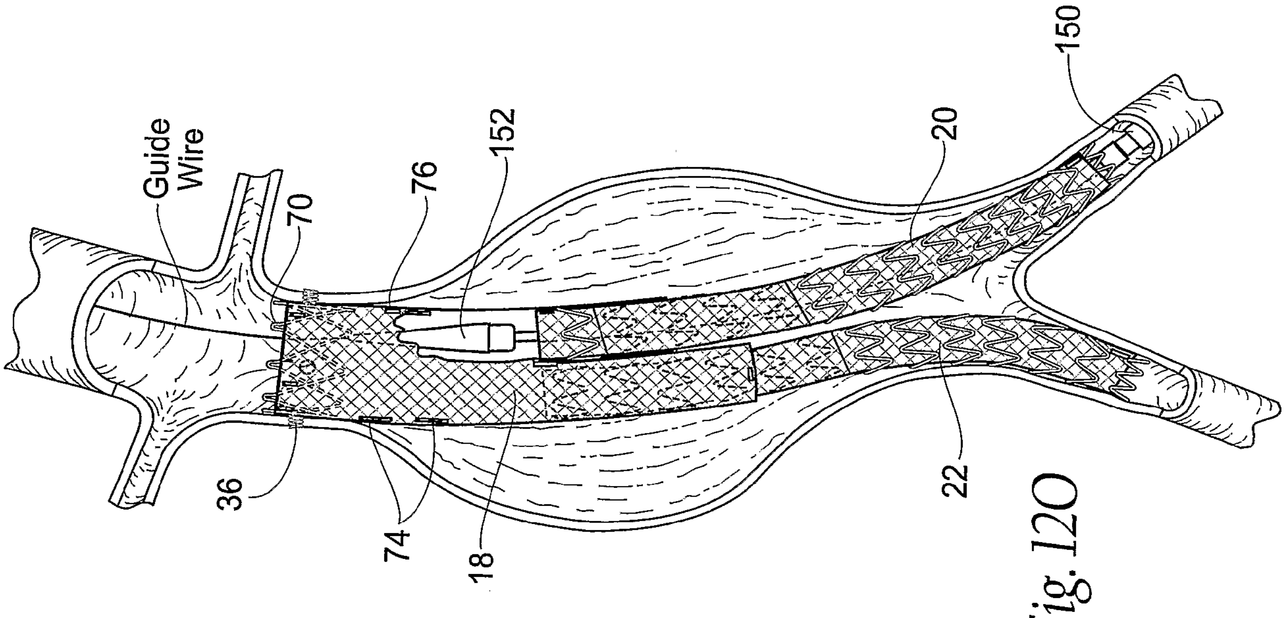
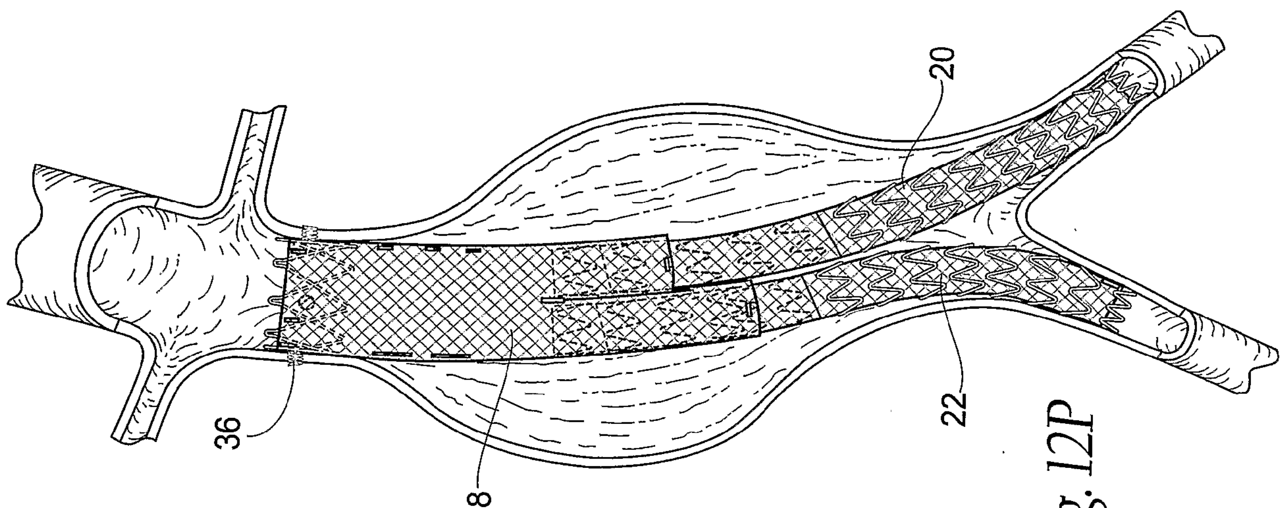


Fig. 12O



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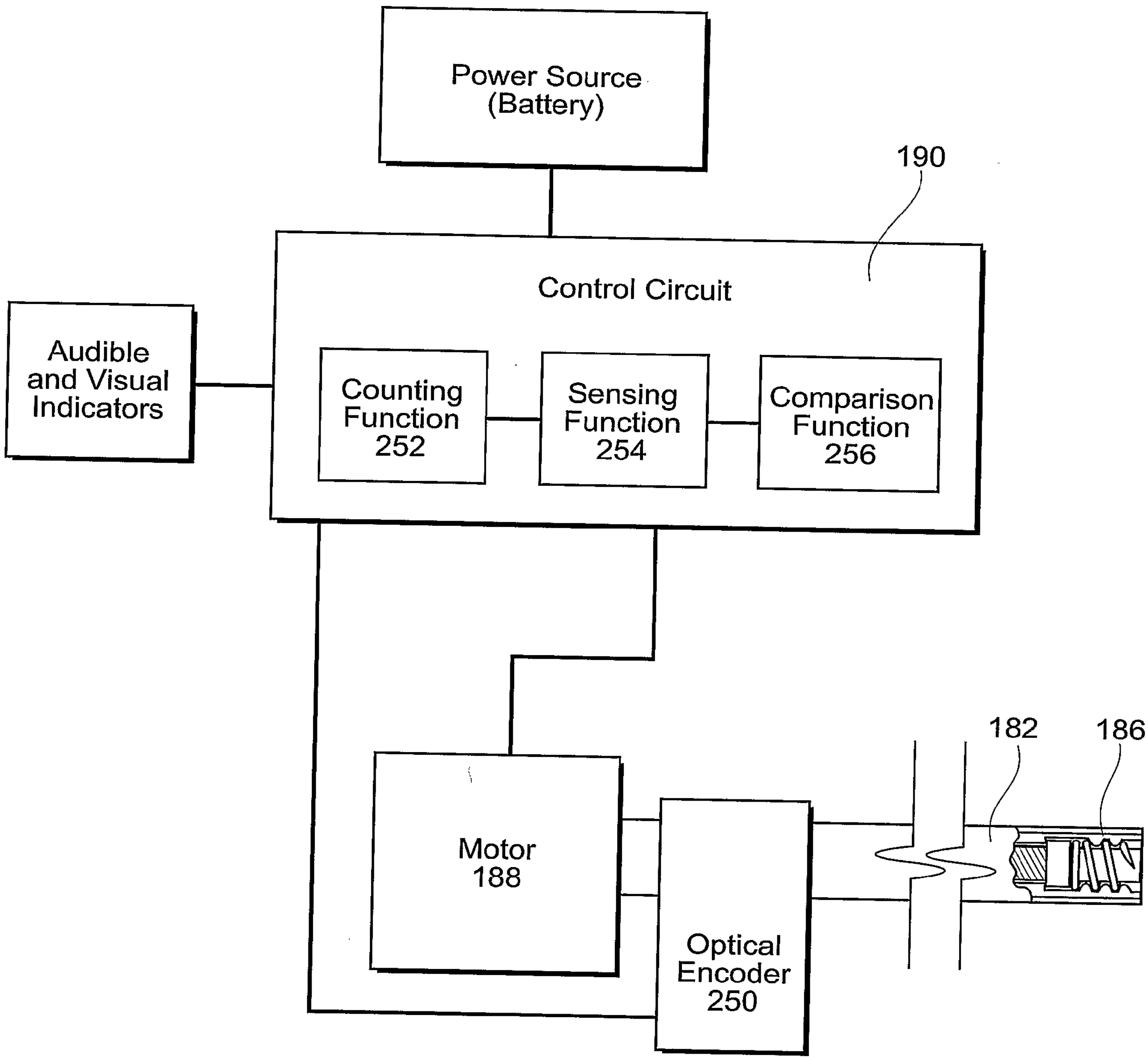
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(Battery)
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Control Circuit
Audible
and Visual
Indicators
Counting
Function
252
Sensing
Function
254
Comparison
Function
256
182
186
Motor
188
Optical
Encoder
250

Fig. 13A

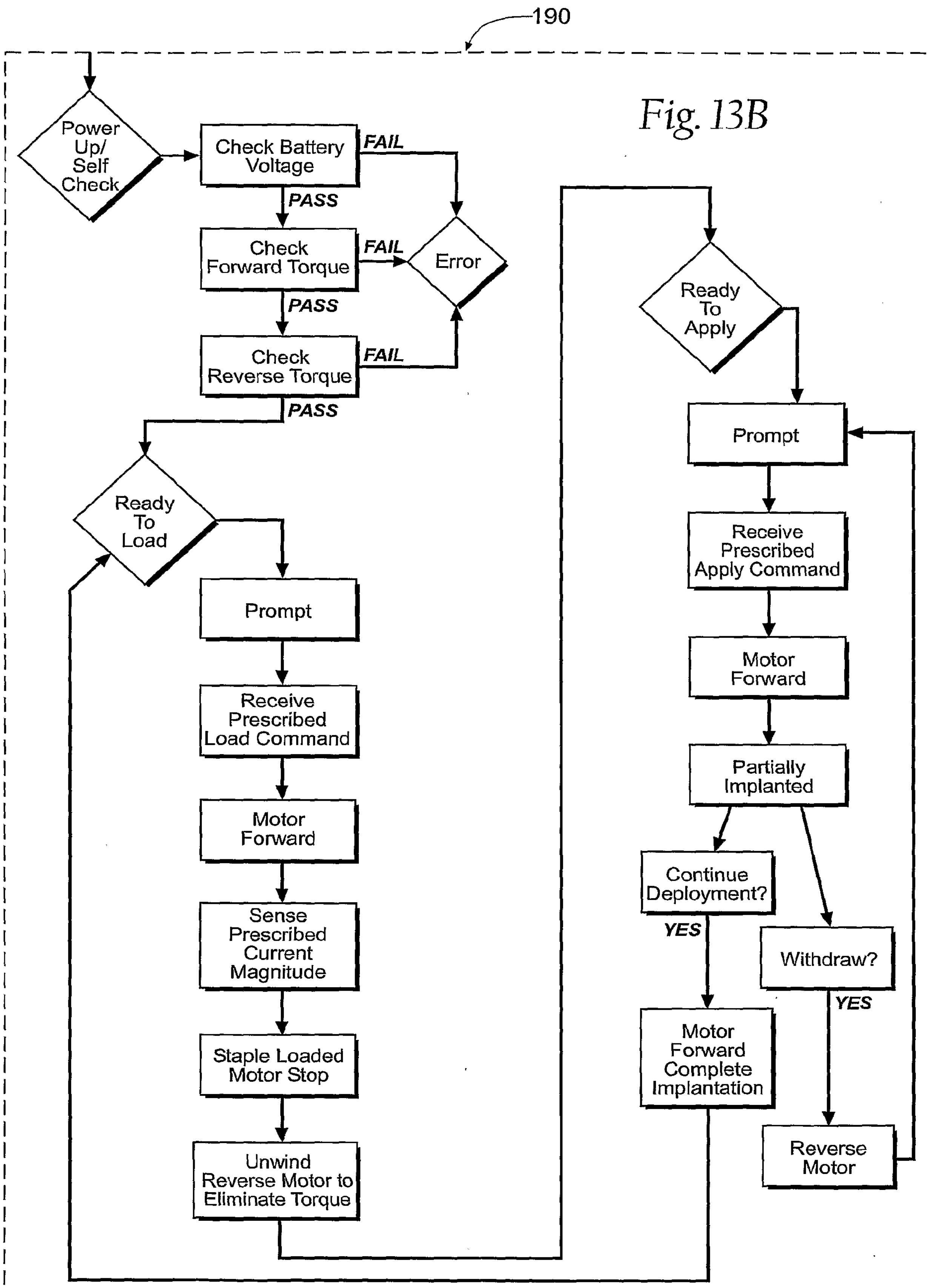
190
Power Up/ Self Check
Check Battery Voltage
FAIL
PASS
Check Forward Torque
FAIL
Error
PASS
Check Reverse Torque
FAIL
PASS
Ready To Load
Prompt
Receive Prescribed Load Command
Motor Forward
Sense Prescribed Current Magnitude
Staple Loaded Motor Stop
Unwind Reverse Motor to Eliminate Torque
Ready To Apply
Prompt
Receive Prescribed Apply Command
Motor Forward
Partially Implanted
Continue Deployment?
YES
Motor Forward Complete Implantation
Withdraw?
YES
Reverse Motor

Fig. 13B

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 April 2007 (26.04.2007)

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11/488,305 18 July 2006 (18.07.2006) US

(71) Applicant *(for all designated States except US)*: **APTUS ENDOSYSTEMS, INC.** [US/US]; 777 North Pastoria Avenue, Sunnyvale, CA 94085 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **JEN, Jimmy** [US/US]; 1406 Antiqua Lane, Foster City, CA 94404 (US). **STAFFORD, Joshua** [US/US]; 1035 Windermere Avenue, Menlo Park, CA 94025 (US). **CHIANG, Andres, L.** [US/US]; 34143 Audrey Court, Fremont, CA 94555 (US). **BOLDUC, Lee** [US/US]; 716 Grape Avenue, Sunnyvale, CA 94087 (US).

(74) Agents: **RYAN, Daniel, D.** et al.; RYAN KROMHOLZ & MANION, S.C., P.O. Box 26618, Milwaukee, WI 53226-0618 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ENDOVASCULAR ANEURYSM DEVICES, SYSTEMS, AND METHODS

(57) Abstract: Devices, systems, and methods for implanting prostheses in the body lumens rely on tacking or anchoring the prostheses with separately introduced fasteners. After initial placement, a fastener applier system is introduced within the expanded prostheses to deploy a plurality of fasteners to at least- one prosthesis" end. The fasteners are usually helical fasteners which are releasably restrained on the fastener driver, and are delivered by rotation of the fastener driver. The fasteners may be applied singly, typically in circumf erentially spaced-apart patterns about the interior of at least one end of the prosthesis. A lumen extension or lumens may be coupled to the prosthesis to extend the reach of the prosthesis within the implantation site. Fasteners may also be applied to the lumen extensions .

WO 2007/047023 A3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 06/37085

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) -- A61F 2/06 (2007.01)
USPC -- 623/1.36, 623/1.11
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC -- 623/1.36, 623/1.11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST -- PGPB,USPT,USOC,EPAB,JPAB; Dialog Classic files 2, 351; Google Patents; USPTO Web Page
Search terms -- catheter guide, fastener applier, instructions, marker indicia, sensor, current, filament, implantation, lumen, controller, actuator, driver, seal, aneurysm

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/0100943 A1 (BOLDUC) 29 May 2003 (29.05.2003); para [0005], [0008], [0009], [0012]-[0014], [0037]	1-29
Y	US 6,273,858 B1 (FOX et al.) 14 August 2001 (14.08.2001); col 6, ln 15-31	1-11
Y	US 2002/0156365 A1 (TSEKOS) 24 October 2002 (24.10.2002); para [0024], [050], [0052], [0069]-[0071], [0075]	9-19
Y	US 2004/0054352 A1 (ADAMS et al.) 18 March 2004 (18.03.2004); para [0032], [0033], [0048]	12-29
Y	US 2004/0002731 A1 (AGANON et al.) 01 January 2004 (01.01.2004); para [0007], [0075]	12-29

☐ Further documents are listed in the continuation of Box C. ☐

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Date of the actual completion of the international search	Date of mailing of the international search report
23 May 2007 (23.05.2007)	30 AUG 2007

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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(71) **Applicant** *(for all designated States except US)*: **APTUS ENDOSYSTEMS, INC.** [US/US]; 777 North Pastoria Avenue, Sunnyvale, CA 94085 (US).

(72) **Inventors; and**
(75) **Inventors/Applicants** *(for US only)*: **BOLDUC, Lee** [US/US]; 716 Grape Avenue, Sunnyvale, CA 94087 (US). **JEN, Jimmy** [US/US]; 1406 Antigua Lane, Foster City, CA 94404 (US).

(74) **Agents**: **RYAN, Daniel, D.** et al.; P.O.Box 26618, Milwaukee, WI 53226-0618 (US).

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(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report (Art. 21(3))*

(54) **Title**: DEVICES, SYSTEMS, AND METHODS FOR ENDOVASCULAR STAPLE AND/OR PROSTHESIS DELIVERY AND IMPLANTATION

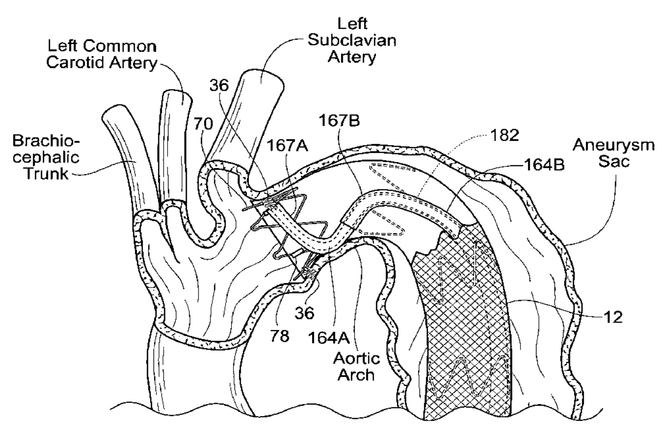

Fig. 13C

(57) **Abstract**: Devices, systems, and methods for implanting expandable prostheses in the body lumens rely on stapling or anchoring the prostheses with separately introduced fasteners. The prostheses may be self -expanding or balloon expandable, and may include a single lumen or more than one lumen. After initial placement, a stapling system is introduced within the expanded prosthesis to deploy a plurality of fasteners to at least one prosthesis end. The stapling system may apply a force to the prosthesis to modify the shape of the prosthesis to conform to the shape of the vessel wall. The stapling system can be deflected in one or more distinct steerable segments. A lumen extension or lumens may be coupled to the prosthesis to extend the reach of the prosthesis within the implantation site. Fasteners may also be applied to the lumen extensions.

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DEVICES, SYSTEMS, AND METHODS FOR ENDOVASCULAR STAPLE AND/OR PROSTHESIS DELIVERY AND IMPLANTATION

Related Applications

This application is a continuation-in-part of co-pending United Stated Patent Application Serial No. 11/488,305, filed July 18, 2006, and entitled "Endovascular Aneurysm Devices, Systems, and Methods."

This application is also a continuation-in-part of co-pending United Stated Patent Application Serial No. 11/255,116, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation."

This application is also a continuation-in-part of co-pending United States Patent Application No. 11/254,619, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Guiding an Operative Tool Into an Interior Body Region."

This application is also a continuation-in-part of co-pending United States Patent Application No. 11/633,724, filed December 5, 2006, entitled "Prosthesis Delivery Systems and Methods," which is a division of United States Patent Application Serial No. 10/692,283, (18379-PROV FOR) filed October 23, 2003 (now United States Patent 7,147,657), and entitled "Prosthesis

Delivery Systems and Methods," which claims the benefit of United States Provisional Patent Application Serial No. 60/488,753, filed July 21, 2003, and entitled "Endoprosthesis Delivery Systems and Methods."

This application also is a continuation-in-part of co-pending United Stated Patent Application Serial No. 10/786,465, filed February 25 2004, and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ."

This application is also a continuation-in-part of co-pending United States Patent Application 11/166,428, filed June 24, 2005, entitled "Multi-Lumen Prosthesis Systems and Methods," which is a division of United States Patent Application Serial No. 10/693,255, filed October 24, 2003 (now United States Patent 6,929,661), which claims the benefit of United States Provisional Patent Application Serial No. 60/489,011, filed July 21, 2003, and entitled "Bifurcated Prosthesis Systems and Methods."

This application also is a continuation-in-part of co-pending United Stated Patent Application Serial No. 10/307,226, filed November 29, 2002, and entitled "Intraluminal Prosthesis Attachment Systems and Methods."

This application is also a continuation-in-part of co-pending United States Patent Application Serial Number 10/669,881, filed September 24, 2003, entitled "Catheter-Based Fastener Implantation Apparatus and Methods with Implantation Force Resolution."

This application is also a continuation-in-part of co-pending United States Patent Application Serial No. 11/166,411, filed June 24, 2005, entitled "Endovascular Aneurysm Repair System," which is a division of United Stated Patent Application Serial No. 10/271,334, filed October 15, 2002 (now United States Patent No. 6,960,217), which claims the benefit of United States

Provisional Patent Application Serial No. 60/333,937, filed November 28, 2001, and entitled "Endovascular Aneurysm Repair System." Each of the preceding applications is incorporated herein by reference.

Field of the Invention

The invention relates generally to devices, systems, and methods for the delivery and implantation of an endovascular staple(s) and/or prosthesis to a targeted site within the body, e.g., for the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel.

Background of the Invention

The weakening of a vessel wall from damage or disease can lead to vessel dilatation and the formation of an aneurysm. Left untreated, an aneurysm can grow in size and may eventually rupture.

For example, aneurysms of the aorta occur in the abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation. Aneurysms can also occur in the tortuous thoracic region between the aortic arch and renal arteries. The rupture of an aortic aneurysm results in massive hemorrhaging and has a high rate of mortality.

Damage or disease of a vessel such as the aorta may also result in a dissection of the vessel wall. Aortic dissections are usually caused by a connective tissue disorder and/or high blood pressure. Left untreated, an aortic dissection can rupture or critically reduce blood flow to the heart, the brain, the spinal cord, the abdominal organs and the legs.

Open surgical replacement of a diseased or damaged section of vessel can eliminate the risk of vessel rupture. In this procedure, the diseased or damaged section of vessel is surgically removed and a prosthesis, made generally in either in a straight or bifurcated

configuration, is installed and then permanently attached and sealed to the ends of the native vessel by suture. The prostheses for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The prostheses are longitudinally unsupported so they can accommodate changes in the morphology of an aneurysm, dissection, and/or the native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co-morbidities.

Endovascular aneurysm and dissection repair has been introduced to overcome the problems associated with open surgical repair. The diseased or damaged section of the vessel is bridged with a vascular prosthesis, i.e., graft, which is placed intraluminally. Typically these prostheses for aortic aneurysms and dissections are delivered collapsed on a catheter through the femoral artery. These prostheses are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel.

Unlike open surgical repair of diseased or damaged sections of a vessel, such as an aortic aneurysm or an aortic dissection, intraluminally deployed prostheses are not sutured to the native vessel, but rely on either barbs or hooks extending from the stent, which penetrate into the native vessel during deployment and require a substantial area of healthy tissue to penetrate, and/or the radial expansion force of the stent itself is utilized to hold the prosthesis in position. These prosthesis attachment means do not provide the same level of attachment when compared to suture and can damage the native vessel upon deployment. In addition, in some areas

the native vessel may include bends or turns, making it difficult for one or both ends of the deployed prosthesis to expand, appose and seal the prosthesis to the vessel wall.

Accordingly, there is a need for improved prosthesis delivery and fastening devices, systems, and methods that deliver and fasten a staple(s) and/or a prosthetic graft within or to a body lumen, the prosthesis being able to adapt to changes in the vessel morphology and able to be deployed and fastened safely and without damage to the native vessel, including a tortuous vessel.

Summary of the Invention

The devices, systems, and methods for delivering and implanting radially expandable prostheses in the body lumens are described. In particular, the present invention provides improved devices, systems, and methods for implanting vascular prostheses into blood vessels, including both arterial and venous systems. In the exemplary embodiments, a variety of tools are used to place prostheses in vasculature to repair and/or reinforce aneurysms and/or dissections, particularly thoracic aortic aneurysms, and aortic dissections.

One aspect of the invention provides devices, systems, and methods including a steerable guide catheter comprising a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool, a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, and a handle assembly.

The handle assembly may comprise a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the first deflecting

means adapted to bend the distal end region in a first articulated position, and a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position. The second articulated position may be different than the first articulated position. The second guide tube may comprise a length that is shorter than the length of the first guide tube. The steerable guide catheter further include an operative tool that applies one or more fasteners to tissue.

Another aspect of the invention provides devices, systems, and methods including a steerable guide catheter comprising a steerable guide catheter comprising a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool, a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating passage of the first guide tube, a first handle assembly comprising a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the first deflecting means adapted to bend the distal end region in a first articulated position, and a second handle assembly comprising a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position.

The second articulated position may be different than the first articulated position. The second guide tube may comprise a length that is shorter than the

length of the first guide tube.

Yet another aspect of the invention provides devices, systems, and methods including a method comprising providing a steerable guide catheter, the guide catheter comprising a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool, a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, and a handle assembly. The handle assembly may comprise a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, and a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position.

Additional steps may include passing the operative tool through the guide catheter, and operating the operative tool while residing in the guide catheter to apply at least one fastener to tissue.

The devices, systems, and methods may further including manipulating the first deflecting means for applying a deflecting force and bending the distal end region of the first guide tube in a first articulated position, and manipulating the second deflecting means for applying a deflecting force and bending the distal end region of the second guide tube in a second articulated position. The second articulated position may be different than the first articulated position.

Yet another aspect of the invention provides devices, systems, and methods including a method comprising providing a first guide tube having a length

and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool, the first guide tube including a first handle assembly comprising a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, providing a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating passage of the first guide tube, the second guide tube including a second handle assembly comprising a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, inserting the first guide tube into the lumen of the second guide tube, advancing the first guide tube until the distal end region of the first guide tube extends beyond the distal end region of the second guide tube, passing the operative tool through the guide catheter, and operating the operative tool while residing in the guide catheter to apply at least one fastener to tissue.

Additional steps may include manipulating the first deflecting means for applying a deflecting force and bending the distal end region of the first guide tube in a first articulated position, and manipulating the second deflecting means for applying a deflecting force and bending the distal end region of the second guide tube in a second articulated position. The second articulated position may be different than the first articulated position.

Yet another aspect of the invention provides devices, systems, and methods including a steerable guide catheter system, the system comprising a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage

of an operative endovascular tool, a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, and a handle assembly.

The handle assembly may comprise a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the first deflecting means adapted to bend the distal end region in a first articulated position, a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position, and instructions for use describing the use of the steerable guide catheter system, the instructions comprising the operations of introducing into a vessel the steerable guide catheter, advancing the steerable guide catheter to the targeted site in the vessel, manipulating the first deflecting means for applying a deflecting force and bending the distal end region of the first guide tube in a first articulated position, and manipulating the second deflecting means for applying a deflecting force and bending the distal end region of the second guide tube in a second articulated position.

The second articulated position may be different than the first articulated position. The operative tool may also be included with the system, the operative tool adapted to apply at least one fastener to tissue while residing in the guide catheter.

The instructions for use may further include instructions comprising passing the operative tool through the guide catheter, and operating the operative tool while residing in the guide catheter to apply at least one fastener to tissue.

Another aspect of the invention provides devices, systems, and methods including a steerable guide catheter comprising a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool, and a handle assembly. The handle assembly may comprise a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the first deflecting means adapted to bend the distal end region in a first articulated position, and a second deflecting means coupled to the distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position.

The second articulated position may be different than the first articulated position. An operative tool may be included that applies one or more fasteners to tissue.

The steerable guide catheter may also include a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, and the second deflecting means coupled to the distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in the second articulated position. The second guide tube may comprise a length that is shorter than the length of the first guide tube.

Brief Description of the Drawings

Fig. 1 is a perspective view of a healthy aorta showing the extent of the aorta from the aortic root,

through the aortic arch, the descending thoracic aorta, and to the abdominal aorta and aortic bifurcation.

Figs. 2A to 2C are perspective views of diseased aortas, showing the extent to which aneurysms may deform the aorta.

Figs. 3A and 3B are perspective views of diseased aortas, showing aortic dissections.

Fig. 4 is a view of the components of a system for repairing an endovascular aneurysm.

Fig. 5 is a view of the components of the system shown in Fig. 4 consolidated for use in a multiple piece kit, along with instructions for their use.

Fig. 6A is a side view of one embodiment of an endovascular graft that forms a part of the system shown in Fig. 4, the supported graft including a most proximal stent extending beyond the proximal edge of the graft.

Fig. 6B is a side view of an additional embodiment of an endovascular graft that forms a part of the system shown in Fig. 4, the unsupported graft including a distal stent and a most proximal stent not extending beyond the proximal edge of the graft.

Fig. 6C is a side view of an additional embodiment of an endovascular graft shown in Fig. 6B, the unsupported graft including a most proximal stent not extending beyond the proximal edge of the graft, and without a distal stent.

Fig. 6D is a side view of an additional embodiment of an endovascular graft that forms a part of the system shown in Fig. 4, the unsupported graft including a proximal portion with a first diameter, and a tapered portion extending to a distal portion have a second diameter smaller than the first diameter.

Fig. 6E is a side view of an additional embodiment of an endovascular graft shown in Fig. 6D, the unsupported graft including a most proximal stent not

extending beyond the proximal edge of the graft, and without a distal stent.

Fig. 6F is a side view of an additional embodiment of an endovascular graft that forms a part of the system shown in Fig. 4, the unsupported graft including a curved portion adapted for placement in a tortuous vessel, and including a most proximal stent not extending beyond the proximal edge of the graft, and without a distal stent.

Fig. 6G is a side view of an additional embodiment of an endovascular graft that forms a part of the system shown in Fig. 4, the supported graft including a graft opening, the graft adapted to allow positioning of the proximal portion of the graft proximal to a branch artery (e.g., the left subclavian artery where healthy tissue may be present for securing the graft, and maintaining fluid flow communication to the branch artery.

Fig. 6H is a close-up view of the opened or fenestrated portion of the endovascular graft shown in Fig. 6G.

Fig. 6I is a perspective view of an additional embodiment of endovascular graft that forms a part of the system shown in Fig. 4, the branched graft includes a small ancillary branch protruding from the side of the graft, the branch 68 adapted to align with a vessel branch.

Fig. 6J is a view of an additional embodiment of endovascular graft that forms a part of the system shown in Fig. 4, the graft including areas adapted for preferential bending/folding, allowing the graft to better conform to angled or tortuous anatomy.

Fig. 6K is a view of the graft shown in Fig. 6J, showing the graft implanted in a tortuous vessel.

Fig. 6L is a view of the graft shown in Fig. 6J, showing the ability of the graft to bend/fold in a multi-curved configuration.

Fig. 6M is a view of the graft shown in Fig. 6J, showing the graft in a compressed configuration, the graft having the ability to be processed to bend/fold at predefined locations.

Fig. 7A is an anatomic view of a representative graft assembly implanted within a descending thoracic aortic aneurysm (TAA).

Fig. 7B is an anatomic view of a representative graft assembly implanted within a descending thoracic aorta, the graft positioned to repair an aortic dissection.

Fig. 8A is a view of the delivery system for the endovascular graft, which forms a part of the system shown in Fig. 4.

Figs. 8B and 8C are perspective views of the top and bottom of the control handle of the delivery system shown in Fig. 8A.

Fig. 8D is an enlarged perspective view of the distal end of the delivery system shown in Fig. 8A, with parts broken away to show the attachment of a supported endovascular graft to the delivery system and the release wire and/or wires and jacket controls that are coupled to the handle to affect a controlled stepwise release of the endovascular graft from the delivery system.

Fig. 8E is a view of the distal end of the delivery system showing the retracted and advanced positions of the slidable release jacket, with an unsupported graft attached to the delivery system.

Fig. 8F is a view of the distal end of the delivery system showing the retracted and advanced positions of the slidable release jacket as shown in Fig. 8E, and showing a supported graft attached to the delivery system.

Fig. 8G is a view of the distal end of the delivery system showing the retracted and advanced positions of

the slidable release jacket as shown in Fig. 8E, and showing an alternative delivery system without stabilizing arms.

Fig. 9 is an enlarged view of a hemostatic seal assembly within the handle of the delivery system, showing the passage of the release wires through the seal assembly between the control mechanisms and the distal end of the delivery system (as shown in Fig. 8D).

Fig. 10A is a perspective view of the first steerable endovascular guide, the second steerable endovascular guide, and the obturator, which make up a steerable endovascular guide system (a two segment guide system is shown) that form a part of the system shown in Fig. 4.

Fig. 10B is a perspective view of the guide tube from the first steerable endovascular guide nested within the second steerable endovascular guide, the nested system adapted to guide the staple applier through at least one resolved angle and to apply an apposition force to conform the shape of the endovascular graft to be secured to the vessel wall.

Fig. 10C is an enlarged view of the handle of the first steerable endovascular guide shown in Fig. 10A.

Fig. 10D is a view of an alternative embodiment of a steerable endovascular guide shown in Fig. 10B, showing the steerable endovascular guide as a single guide device incorporating the features of the first steerable guide and the second steerable guide.

Fig. 10E is a view of an additional alternative embodiment of a steerable endovascular guide, showing the steerable endovascular guide as a single handle guide device with a single steerable guide tube adapted for steering in multiple directions.

Fig. 11A is a view of an endovascular fastener or staple that forms a part of the system shown in Fig. 4.

Fig. 11B is a view of a cassette to hold a plurality of endovascular fasteners, as shown in Fig. 11A, and to present the fasteners for loading in the staple applier, which also forms a part of the system shown in Fig. 4.

Fig. 12A is a view of a fastener applier for implanting a fastener as shown in Fig. 11A, which forms a part of the system shown in Fig. 4.

Fig. 12B is an enlarged view of the handle of the fastener applier shown in Fig. 12A, and showing the controls available to the user.

Fig. 12C is a view showing the manipulation of the fastener applier shown in Fig. 12A in loading a fastener from the cassette shown in Fig. 11B.

Fig. 13A is an anatomic view showing the driven member at the distal end of the fastener applier (and positioned within the catheter of the two segment steerable guide system) prior to being driven to implant a fastener in a graft and adjacent tissue, to secure the position of the graft, and showing the two segment steerable guide system adapted to guide the fastener applier through at least one angle to reach tortuous locations for fastener implant.

Figs. 13B and 13C are anatomic views as shown in Fig. 13A, showing the fastener applier positioned within the two segment steerable guide system, the steerable guide system being used to apply an apposition force to the endovascular graft to deflect a portion of the graft against the vessel wall where the graft may not naturally lay flat, modifying the shape of the endovascular graft to conform to the vessel wall, and then implanting a fastener in the graft and adjacent tissue, to secure the position of the graft.

Fig. 14A is a view showing a fastener applier of a type shown in Fig. 12A, which includes indicia visible to a naked eye.

Fig. 14B is a view showing the fastener applier shown in Fig. 14A nested within the two segment steerable endovascular guide system of a type shown in Fig. 10B, showing how the indicia, which is visible to a naked eye, marks when the driven member rests at a desired distance within the steerable guide system just short of the terminus of the guide tube of the first steerable guide and therefore out of contact with tissue.

Fig. 14C is a close-up view showing the distal end of the two segment steerable guide system when the indicia visible at the proximal portion of the applier catheter marks when the actuated member rests at a desired distance within the first guide tube short of the terminus of the first guide tube and therefore out of contact with tissue.

Fig. 15A is a schematic view of the motor control functions of a representative control circuit for the fastener applier shown in Fig. 12A.

Fig. 15B is a schematic flow diagram of the operational states of the control circuit shown in Fig. 15A.

Figs. 16A to 16K are anatomic views of manipulation of the components of the system shown in Fig. 4 in placing a prosthesis in a descending thoracic aortic aneurysm, which manipulations can be incorporated within an instruction for use associated with a kit like that shown in Fig. 5.

Figs. 17A to 17C are anatomic views of manipulation of components of the system shown in Fig. 4 in repairing an aortic dissection in the descending thoracic aorta using staples and without a graft, which manipulations can be incorporated within an instruction for use associated with a kit of components like that shown in Fig. 5.

Figs 18A and 18B are anatomic views showing an

alternative graft assembly comprising three graft assemblies nested together to extend the length of the implanted graft.

Description of the Preferred Embodiment

Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention which may be embodied in other specific structures. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

This specification discloses various catheter-based devices, systems, and methods for delivering and implanting staples and prostheses, including radially expandable prostheses in the body lumens. For example, the various aspects of the invention have application in procedures requiring the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel. The devices, systems, and methods that embody features of the invention are also adaptable for use with systems and surgical techniques that are not necessarily catheter-based.

The devices, systems, and methods are particularly well suited for treating aortic dissections and aneurysms of the aorta, including those that occur in the thoracic region between the aortic arch and renal arteries, as well as aneurysms that also occur in the abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation. For this reason, the devices, systems, and methods will be described in this context. Still, it should be appreciated that the disclosed devices, systems, and methods are applicable for use in treating other dysfunctions elsewhere in the body, which are not necessarily aorta-related.

When referring to a prosthesis, i.e., an endovascular graft or its components that are intended to be implanted in a vessel or body organ, the terms "proximal" and "distal" will be used to describe the relation or orientation of the graft with respect to the heart after implantation. Therefore, the term "proximal" will be used to describe a relation or orientation of the graft that, when implanted, is toward the heart, and the term "distal" will be used to describe a position or orientation of the graft that, when implanted, is away from the heart, i.e., toward the feet.

When referring to implantation apparatus or devices that are manipulated by a physician or operator in order to implant the endovascular graft or its components, the terms "proximal" and "distal" will be used to describe the relation or orientation of the apparatus or device with respect to the operator as it is used. Therefore, the term "proximal" will be used to describe a relation or orientation of the apparatus or device that, when in use, is positioned toward the operator (i.e., at the handle end of the device), and the term "distal" will be used to describe a position or orientation of the apparatus or device that, when in use, is positioned away from the operator (i.e., at the other end of a catheter or the like away from the handle).

I. Aortic Abnormalities

A healthy aorta, the body's largest artery, has a general shape like the handle portion of a walking cane (see Fig. 1). The short length of the curved handle comes out of the heart and curls through the aortic arch. Multiple smaller arteries branch off at the aortic arch to serve the head and arms. The aorta continues to descend through the chest cavity into the abdomen and separates to provide blood to the abdominal organs and both legs. Various abnormalities may affect the aorta,

most of which are considered potentially life-threatening. Prevalent aortic abnormalities include aortic aneurysms and aortic dissections, as non-limiting examples.

Aneurysms may affect one or more segments of the thoracic aorta, including the ascending aorta, the arch, and the descending thoracic aorta. A thoracic aortic aneurysm (TAA) can be described as an expanded (bulging) section(s) of the wall of the aorta, and is considered a life-threatening condition. Thoracic aortic aneurysms of any size can cause significant short- and long-term mortality due to rupture and dissection. Figs. 2A, 2B, and 2C show examples of aortas having diseased tissues and difficult cases where the left subclavian artery ostium is distal to the aortic arch. Relative positions of the aneurysmal tissues in the tortuous aortic arch can be seen, as can and relationship to the brachiocephalic trunk, left common carotid artery, and the left subclavian artery. Often the left subclavian artery provides a landmark for positioning of an endovascular graft (to be described in greater detail below).

Common causes of a thoracic aortic aneurysm include hardening of the arteries (atherosclerosis), degeneration of the media of the aortic wall, as well as from local hemodynamic forces. Additional risk factors include various connective tissue disorders such as Marfan syndrome, previous dissection of the aorta, and trauma such as falls or motor vehicle accidents. They also sometimes occur in people who have bicuspid aortic valves.

An aortic dissection is a perforation or tear in the lining of the aorta. The tear allows blood to flow between the layers of the aortic wall, with the force of the blood forcing the layers of the wall apart. Figs. 3A and 3B show views of aortic dissections. An aortic

dissection is a medical emergency and can quickly lead to death. If the dissection tears the aortic wall completely open, massive and rapid blood loss occurs.

The tearing of the inner lining of the aorta causes the blood to separate along the wall of the artery. This generally causes two channels in the vessel, with one channel referred to as the true channel and the other channel referred to as the false channel. As can be seen in Figs. 3A and 3B, the tear allows the blood to create the false channel. With each heartbeat, the artery may progressively tear more and more with blood propagating down the false channel blocking off the true channel and the flow of blood to some or all of the branches of the aorta.

Aortic dissections can be classified by the Stanford method into a type A or type B depending on the location and the extent of the dissection. Type A dissection, or proximal dissection, involves the ascending aorta and aortic arch, and may or may not involve the descending aorta. Type B dissection, or distal dissection, usually begins just distal to the ostium of the left subclavian artery, extending distally into the descending and abdominal aorta. If left untreated, the risk of death from aortic dissection can reach 30 percent within fifteen minutes after onset of symptoms and 75 percent by one week.

II. SYSTEM OVERVIEW

Aortic abnormalities, such as thoracic aortic aneurysms and aortic dissections with the appropriate anatomy, may now be repaired by the implantation of an endovascular prosthesis or graft. The implantation of staples alone may also be used for the repair of aortic dissections. Fig. 4 shows an exemplary system 10 for repairing an aortic abnormality. By way of example, the system 10 and/or components of the system are well suited

for the repair of a descending thoracic aortic aneurysm and/or an aortic dissection, and will be described in this context. The system 10 comprises three primary components 12, 14, and 16.

The first component comprises an endovascular prosthesis or graft assembly 12. In use, the endovascular graft 12 is placed within a vessel at the site of the aortic abnormality. The endovascular graft 12 serves to exclude a portion of the vascular system from blood flow and blood pressure. In order to obtain exclusion of a portion of the vascular system, the endovascular graft must be sealed against the vascular wall, which requires apposition between the endovascular graft 12 and the vascular wall. The endovascular graft 12 must also be prevented from moving or migrating from its deployed position within the vascular system.

In the illustrated embodiments, the endovascular graft 12 is placed and secured within the aortic arch, e.g., at or near the left subclavian artery and extends past the site of the aneurysm and into the descending aorta (see Fig. 7A). Fig. 7B shows the endovascular graft 12 placed and secured within the descending aorta and extending past the site of a dissection. Additional embodiments of a graft assembly 12 are shown in Figs. 6B through 6M.

The second component 14 comprises an endovascular delivery system for introducing and deploying the endovascular graft 12 using an endovascular approach. In the illustrated embodiment, in which the endovascular graft 12 comprises a single lumen body, a single endograft delivery component 24 may be provided. In alternative embodiments incorporating modular endovascular graft components, there may be individual corresponding endograft delivery components provided.

The third component 16 comprises an endovascular

stapling system. In one embodiment, the endovascular stapling system 16 may be used to attach one or more regions of the endovascular graft 12 to the vessel wall with one or more endovascular staples. The endovascular stapling system 16 may also be used for implanting one or more endovascular staples without including an endovascular graft 12, the endovascular staples serving to close the entrance of the dissection to blood flow.

In one embodiment, the endovascular stapling system 16 comprises a steerable endovascular guide system 30 comprising a first steerable guide 30A and a second steerable guide 30B, an obturator 32, a cassette 34 holding a plurality of endovascular staples 36, and an endovascular fastening device, i.e., a staple applier 38. In an alternative embodiment, the two steerable guide catheters 30A and 30B may be combined into one operational handle with two steerable guide catheters. The steerable endovascular guide system 30 is sized and configured to provide at least one angle, rotational positioning, and relative positioning (axially) between the two guide catheters and preferably two or more angles with rotational positioning and relative positioning between the two guide catheters.

In use, the steerable endovascular guide system 30 establishes an endovascular path to the targeted site where the endovascular graft 12 has been positioned, and may be partially or fully deployed. The steerable endovascular guide system 30 is adapted to be manipulated by flexure and rotation in at least one direction or angle to provide the staple applier 38 access to successive sites, including difficult to reach sites due to tortuous anatomy of the vessel. The endovascular staple applier 38, carrying one or more endovascular staples 36, is guided by the two segment (30A and 30B) steerable endovascular guide system 30 to the successive

sites. Once positioned, individual endovascular staples 36 are implanted, to penetrate the endovascular graft 12 (if used) and adjacent vessel wall. The endovascular staple applier 38 is actuated to implant individual endovascular staples 36 into selected region or regions of the endovascular graft 12 and adjacent vessel wall, to attach the endovascular graft 12 to the vessel wall.

The stapling system is adapted to apply an apposition force, i.e., resolution of force, to the endovascular graft 12 to modify the shape or form of the endovascular graft to conform to the shape of the vessel wall. This resolution of force can be utilized to deflect a portion or portions of the endovascular graft against the vessel wall to implant an endovascular staple, i.e., a fastener. After the conformance is obtained, a fastener or fasteners are implanted through the endovascular graft 12 and into the vessel wall. The fastener(s) maintain the shape of the modified configuration of the endovascular graft. This modified shape enables the endovascular graft 12 to obtain apposition between the graft 12 and the tortuous wall(s) of the vessel, and to exclude a portion of the vascular system.

III. SYSTEM KIT

As Fig. 5 shows, the various tools and devices as just described, comprising the system 10, can be consolidated for use in a multiple piece functional kit 40. It is to be appreciated that the various tools and devices are not necessarily shown to scale.

The kit 40 can take various forms. In the illustrated embodiment, the kit 40 comprises an assemblage of individual packages 42, 48, 50, 52, 54, and 56, each comprising a sterile, packaged assembly. One or more of the packages may include an interior tray or card made, e.g., from die cut cardboard, plastic sheet, or thermo-formed plastic material, which hold the contents.

The kit 40 also preferably includes instructions or directions 58 for using the contents of the packages to carry out a desired procedure. A desired procedure using the contents of the kit 40 shown in Fig. 5 will be described in greater detail later.

The instructions for use 58 can, of course vary. The instructions for use 58 can be physically present in one or more of the packages, but can also be supplied separately. The instructions for use 58 can be embodied in separate instruction manuals, or in video or audio recordings. The instructions for use 58 can also be available through an internet web page.

A. The Component Packages

The arrangement and contents of the packages can vary. For example, as shown in Fig. 5, the kit 40 comprises six packages 42, 48, 50, 52, 54, and 56, and instructions 58. Three of these packages 42, 48, and 50 provide the main components of the endovascular repair system 10 as described. The remaining packages 52, 54, and 56 provide ancillary components used in the deployment of the system 10, e.g., conventional vascular access sheaths (in package 52); conventional 0.035 inch guide wires (in package 54); and bags containing heparinized saline for catheter flushing and contrast for angiography (in package 56).

In package 42, the endovascular graft 12 is preloaded into the endograft delivery component 24. Housed within the package 42, the endovascular graft 12 and the corresponding delivery component 24 for the endovascular graft are supplied sterile to the user.

As further shown in Fig. 5, the kit 40 comprises an additional package 50 that provides the two segment (30A and 30B) steerable endovascular guide system 30 and at least one associated component; namely, the obturator 32. As previously described, the steerable endovascular guide

system 30 may also comprise a single device having the combined features of the two separate catheters. The kit 40 also comprises an additional package 48 that provides the endovascular staple applier 38 and at least one associated component; namely, a cassette 34 holding a plurality of endovascular staples 36. Housed within the packages 48 and 50, the two segment steerable endovascular guide system 30 and the endovascular staple applier 38 and their associated components are supplied sterile to the user.

IV. SYSTEM COMPONENTS

A. The Endovascular Graft

In representative embodiments (see Figs. 6A through 6M), the endovascular graft 12 is a single lumen endograft generally comprising two primary components: a graft 60 made of a biocompatible material, e.g., polyester, ePTFE, etc.; and optionally a most proximal stent or scaffold 70 made of a biocompatible metal or plastic material, e.g., stainless steel, nickel-titanium (Nitinol), etc. One or more stents or scaffolds 62 may also be included in the graft mid-body for additional support (supported graft). Supported grafts (with one or more stents 62) and unsupported grafts are possible. In addition, a distal stent 63 may or may not be included.

In a representative embodiment, the preferred length of the endovascular graft 12 is between 5 cm and 30 cm and most preferably between 10 cm and 25 cm. Although, it is to be appreciated that other lengths, such as 15 and 20 cm for example, are possible to accommodate different anatomic conditions and vessel abnormalities. Desirably, a range of dimensions for the diameter of the graft 12 are provided to accommodate different anatomic dimensions of patients.

The endovascular graft 12 may include a most proximal stent 70, e.g., with diamond or "V" shaped

cells, which may be sewn to the inside or outside of the proximal portion 65 of the graft e.g., with braided or monofilament suture. The most proximal stent 70 is sized and configured to accommodate secure apposition to the vessel wall, for example, at the level of the aortic arch just below, or just beyond the left subclavian artery. At this tortuous location, the graft 12 and/or stent 70 may resolve to a more elliptical or oval shape, due to the curvature of the proximal portion of the endovascular graft within the aortic arch, which may bend or curve 90 degrees or more. The stapling system 16 is adapted to apply an apposition force to deflect a portion or portions of the proximal portion 65, or other portions of, the graft 12 and/or the stent 70 against the vessel wall where the graft 12 does not naturally appose the vessel wall due to the curvature of the vessel wall, to conform the shape of the endovascular graft 12 to the vessel wall at the desired location to be secured. The ability to deflect a portion or portions of the endovascular graft is desirable because it allows the shape of the graft 12, or portions thereof, to be customized to the patient's anatomy.

In the embodiment shown in Fig. 6A, the stent 70 extends beyond the fabric, with the extension ranging from about 0.0 mm to about 15 mm, although a wider range is possible. A supporting stent 62 is shown in the graft 12. In an alternative embodiment shown in Fig. 6B, the stent 70 does not extend beyond the fabric. The grafts in Figs. 6B and 6C are shown as an unsupported graft with a distal stent 63 and without a distal stent 63, respectively.

Additional embodiments of the graft 12 are possible to address a variety of anatomical configurations. Fig. 6D shows an unsupported tapered graft 12 wherein the proximal portion 65 includes a first diameter D1, and the

distal portion 66 includes a second diameter D2. The first diameter may be greater than the second diameter in one embodiment and less than the second diameter in an alternative embodiment. The grafts in Figs. 6D and 6E are shown as an unsupported graft with a distal stent 63 and without a distal stent 63, respectively.

Fig. 6F shows one embodiment of a curved graft 12 configuration. The curved graft may be used to aid in conformance with placement in the aortic arch or other tortuous locations. As a non-limiting example, the curved graft 12 is shown without the use of the distal stent. The curved graft may be initially woven in a straight configuration, and then processed (i.e., heat set on a curved mandrel) to take the predetermined curved shape.

Fig. 6G shows an additional alternative embodiment of the graft 12. The graft 12 includes an opening 67 in the proximal portion 65 which could accommodate fluid communication with a branch artery such as the left subclavian artery, for example, and allow the graft 12 to land further proximally in the thoracic aorta, where healthy tissue may be more readily available to secure the graft 12.

Fig. 6I shows another alternative embodiment of the graft 12. The branched graft 12 includes a small ancillary branch 68 protruding from the side of the graft, the branch 68 adapted to align with a vessel branch, such as the subclavian artery.

Figs. 6J to 6M show yet another alternative embodiment of a graft 12. The tubular graft 12 includes areas 72 for preferential bending/folding. These preferential bending/folding areas 72 allow the graft 12 to better conform to angled or tortuous anatomy. In addition, the preferential bending/folding areas 72 bias the folds 74 in a direction that is most advantageous for blood flow (i.e., the folds go in the direction of blood

flow). The preferential bending/folding areas 72 may also eliminate or reduce the contact between individual stents 62 (i.e., metal scaffolding components) when the graft is placed in angled or tortuous anatomy.

As can be seen in Fig. 6J, the graft 12 includes sufficient unstented graft areas 72 in-between the stents 62 in order to allow the bending/folding to occur. The width of the unstented graft area 72 may vary depending on the application and/or the location of implantation (see Fig. 6K for example). Figs. 6K and 6L show the graft 12 in various curved configurations. As can be seen, the graft 12 is adapted to bend/fold (i.e., compress) at or near the inner radius of the curve, while the unstented graft area 72 at or near the outer radius of the curve is allowed to expand as needed.

The graft 12 may be preconfigured so the graft bends/folds at the unstented graft areas 72 as desired. A compressive force may be applied to successive stents 62 while radially pinching or squeezing the leading edge of one stent 62, to cause it and the unstented graft material 72 between the two stents to fold within the other stent 62. Using this method, the graft 12 may be partially or completely compressed as shown in Fig. 6M. Time and/or temperature may then be used to process the graft 12 to bend/fold in a predetermined manner. The bends/folds in the graft 12 may be made permanent with time and/or temperature configurations. Generally, the lower the temperature the longer the time it takes to achieve a desired configuration. In a preferred embodiment, a temperature between about 10 degrees Celsius to about 250 degrees Celsius may be used, and more preferably between about 30 degrees Celsius to about 150 degrees Celsius. The graft may be processed to varying levels of conformity using a range of times from about 1 second to several days.

The graft 12 may include stents 62, shown with diamond or "V" shaped cells, which may be sewn to the inside or outside of the graft, e.g., with braided or monofilament suture.

Predetermined arrays of radiopaque markers made from biocompatible materials with high radiopacity (e.g., tantalum, platinum or gold) are desirably attached to the endovascular graft 12 to assist with visualization under fluoroscopy. The markers, like the stents, may be sewn to the graft, e.g., with braided or monofilament suture or can be attached to the stent. The arrays can vary. In the illustrated embodiments, there are four (4) proximal stent marker bands 78 and four (4) distal stent marker bands 80, although other combinations and positions are possible to aid in the placement of the graft.

Further details of representative constructions of the endovascular graft 12 can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,444, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including a Prosthesis Assembly," which is incorporated herein by reference.

B. Endovascular Graft Implantation Components

1. The Endovascular Graft Delivery System

a. General Overview

The endovascular graft assembly 12 is preloaded into the delivery system 24 (see Fig. 8A), which is a single use component that is supplied to the user within its package 42 in a sterile condition (see Fig. 5). The delivery system 24 is sized and configured to facilitate accurate placement of the endovascular graft 12 and to allow the physician to maintain control of the endovascular graft 12 while the endovascular staples 36 are applied.

In the illustrated embodiment, the delivery system

24 comprises a delivery catheter 96 and a control handle 98 coupled to the proximal end of the delivery catheter 96. The delivery catheter 96 (see Fig. 8D) comprises a flexible inner assembly 100 and an outer graft retention jacket 102. The inner assembly 100 carries at its distal-most end a flexible radiopaque tracking nosecone 104.

When preloaded (see Fig. 8D), the endovascular graft 12 (a supported graft 12 is shown) may be attached to the inner assembly 100 in discrete locations. In this non-limiting example, the graft is attached in three locations, just proximal of the nosecone 104 (i.e., toward the handle 98), the proximal portion 65 of the graft may be secured by a releasable suture S1 to the inner assembly 100. Also just proximal of the nosecone 104, the inner assembly 100 may include a set of stabilizing arms 106 (or a releasable suture). In the illustrated embodiment, there are three stabilizing arms 106. The proximal portion 65 of the preloaded endovascular graft 12 may be attached to the three stabilizing arms by three releasable pull wires S2, each threaded through eyelets in a respective one of the distal ends of the stabilizing arms 106 and through adjacent graft material. The distal end 66 of the preloaded endovascular graft 12 may also be attached to the inner assembly 100 by a releasable suture S3. These sutures S1, S2, and S3 and release wires 108, 110, and 112 (or other release means) secure the endovascular graft 12 to the inner assembly 100 for deployment to the targeted implantation site.

In an alternative embodiment, the graft 12 can be attached to the inner assembly 100 in multiple discrete locations without using the proximal stabilizing arms. It is also to be appreciated that the stabilizing arms are not limited to attaching only the proximal portion 65 to the inner assembly 100. Stabilizing arms may be used to

attach any portion of the graft 12 to the inner assembly, including the most proximal stent 70, a distal stent 63, the proximal portion 65, the distal portion 66, or any other portion of the graft 12.

The separate release wires 108, 110, and 112 extend from the handle 98 along the inner assembly 100 (see Fig. 9). The separate release wires 108 and 112 are independently coupled to the respective suture S1 holding the most proximal stent 70 (release wire 108), and the suture S3 at the distal portion 66 of the endovascular graft 12 (release wire 112). The release wires 110 are continuations of the release wires S2 threaded through the stabilizing arms 106 (as previously described), so that, in the illustrated embodiment, there are actually three release wires 110, one for each arm 106. Controls 114, 116, and 118 on the handle 98 are coupled to the separate release wires 108, 110 (commonly coupled to the three wires), and 112, as will be described in greater detail later, to independently release the sutures or release wires at one location, without necessarily releasing the sutures or release wires at another location. The separate and independently controllable release wires 108, 110, and 112 make possible the release of the endovascular graft 12 in a prescribed order, to deploy the endovascular graft 12 in a desired sequence during the graft deployment process, as will be described in greater detail later.

The graft retention jacket 102 is sized and configured to slide over and along the inner assembly 100 from an advanced position over the preloaded endovascular graft 12 (shown in phantom lines in Fig. 8E) to a retracted position spaced away from the preloaded endovascular graft 12 (shown in solid lines in Fig. 8E). Fig. 8E shows an embodiment of an unsupported graft, and Fig. 8F shows an embodiment of a supported graft. One or

more radiopaque marker(s) 120 is positioned at or near the leading edge of the graft retention jacket 102 to assist in visualization under fluoroscopy.

As can be seen in Figs. 8B and 8C, a jacket control mechanism 122 coupled to controls 124 and 126 on the handle 98 affects retraction of the graft retention jacket 102 in a stepwise fashion -- using first control 124 and then control 126, as will be described later -- as well as the re-advancement of the retention jacket 102 using the single control 126 after the graft 12 has been fully deployed and it is time to withdraw the delivery system.

When in its advanced position, the graft retention jacket 102 protects the preloaded endovascular graft 12 as it is advanced through the patient's vasculature. When in its retracted position, the graft retention jacket 102 frees the preloaded endovascular graft 12 for deployment by operation of the controls 124 and 126 on the handle 98 during the graft deployment process.

The actuating means on the control handle 98 (see Figs. 8B and 8C) may include a jacket retraction knob 124 and a jacket retraction slide 126, which are coupled to the jacket control mechanism 122 just described. The jacket retraction knob 124 is actuated by rotation and is coupled to gear components of the jacket control mechanism 122 within the handle 98. The gear components apply a mechanical advantage in response to rotation of the knob 124 sufficient to overcome the resistance of the graft retention jacket 102 to axial movement beyond the proximal portion of the graft and optionally the mid-body stent(s) 62, when included, of the endovascular graft 12. Once passed the proximal portion of the graft, the gear components of the jacket control mechanism 122 may be automatically released from the jacket retraction knob 124 (the knob 124 will accordingly spin freely), and

subsequent control passes to the jacket retention slide 126. Pulling on the jacket retention slide 126 (which may not provide a mechanical advantage) suffices to complete the retraction of the jacket 102. This control sequence provides the physician with tactile feedback during the retraction of the jacket 102. After retracted in this manner, the jacket 102 can be advanced back toward the nosecone 104 using the jacket slide 126 when it is time to withdraw the delivery system after release of the graft 12.

In an alternative embodiment of the jacket control mechanism 122 within the handle 98, the delivery system 24 may have the ability to produce a mechanical advantage for the full length of the retraction of the graft retention jacket 102. The mechanical advantage produced may be disengaged by the physician at any point during the retraction of the jacket 102, and the mechanical advantage may be reengaged if desired, at any point during the retraction of the jacket 102. The mechanical advantage may be produced using the gear system as described, or may be produced by other means such as a reel and cable system, or an exterior threaded rod with an internal threaded component for example.

As previously described, the actuating components on the control handle may include the proximal release slide 114, the graft release slide 116, and the distal release slide 118. The proximal release slide 114 is coupled to the release wire 110 for the proximal portion 65 of the graft. The graft release slide 116 is coupled to the three separate release wires 110 for the stabilizing arms 106. The distal end release slide 118 is coupled to the separate release wire 112 for the distal portion 66 of the endovascular graft 12.

Once the graft retention jacket 102 is retracted (as just described), pulling on the proximal release slide

114 opens the proximal portion 65 of the graft. Pulling on the distal end release slide 118 opens the distal portion 66 of the endovascular graft 12. Despite opening the proximal portion 65 and the distal portion 66, the proximal portion 65 of the endovascular graft 12 remains attached to the inner assembly 100 of the endovascular graft delivery system. The physician maintains control of the endovascular graft 12 for further final positioning and for the application of the staples 36, as will be described in greater detail later.

Once positioned in a desired location and/or after insertion or implantation of staples to secure the endovascular graft 12 to the vessel wall, pulling on the graft release slide 116 releases the endovascular graft 12 from the stabilizing arms 106 and the delivery catheter 96.

An alternative embodiment of the delivery catheter 96 is shown in Fig. 8G without stabilizing arms. In this embodiment, the endovascular graft 12 (an unsupported graft 12 is shown) may be attached to the inner assembly 100 at discrete locations. In this non-limiting example the graft is attached in two locations, just proximal of the nosecone 104, (i.e., toward the handle 98), with the proximal portion 65 of the endovascular graft 12 being secured by a releasable suture S1 to the inner assembly 100, and the distal end of the preloaded endovascular graft 12 may also be attached to the inner assembly 100 by a releasable suture S3. These sutures S1 and S3 secure the endovascular graft 12 to the inner assembly 100 for deployment to the targeted implantation site, as previously described. It is to be appreciated, as previously described, that the graft 12 can be attached to the inner assembly 100 in multiple discrete locations, and without using the proximal stabilizing arms, to maintain control of the graft 12. The use of release

wires, for example, as described above may be used to attach the graft 12 to the inner assembly 100 to maintain control of the graft 12 while implantation of staples takes place.

If desired, and as shown in phantom lines in Fig. 8A, a stationary outer jacket 220 may be provided that extends for a distance from the proximal end of the handle 98 over the delivery catheter 96 (the jacket 102), which slides within the stationary outer jacket 220. The stationary jacket 220 provides a seal interface with a hemostatic valve of the introducer sheath at the access site. The stationary jacket 220 can be made of a suitable medical grade plastic, such as Fluroinated Ethylene Propylene (FEP) as a non-limiting example. The stationary outer jacket 220 provides column strength and lubricity to reduce friction during sliding actuation of the jacket 102.

In a representative embodiment, the handle 98 (e.g., near the sliding controls 114, 116, and 118 just described) includes a hemostatic seal assembly 128. As Fig. 9 shows, a flush passage 130 (for conveying heparinized saline to flush the delivery catheter 96 prior to deployment) communicates with the space between the inner assembly 100 and jacket 102 through the hemostatic seal assembly 128. As Fig. 9 also shows, the individual release wires 108, 110, and 112 for the proximal portion release slide 114, the graft release slide 116 (one release wire 110 for each stabilizing arm 106), and the distal end release slide 118, as previously described, also pass from the slide controls 114, 116, and 118 within the handle in a sealed fashion through the hemostatic seal assembly 128 for passage along the inner assembly 100 to the distal end of the delivery catheter 96, where they connect to their respective components, as previously described. The hemostatic seal assembly 128

allows flushing to occur and prevents blood, which can enter the space between the outer jacket 102 and the inner assembly 100 catheter tube during use, from entering the interior of the handle 98.

The delivery catheter 96 is desirably sized to present a minimum diameter according to the diameter of the endovascular graft 12 it carries. The delivery catheter 96 is desirably sized and configured with a lumen accommodating conventional over-the-wire delivery within a patient's vasculature, e.g., using a conventional 0.035 or 0.038 inch guide wire. In a representative embodiment, the overall length of the delivery catheter 96 (not including the handle 98) is preferably between 40 and 120 cm and most preferably between 60 and 110 cm.

Further details of representative constructions of a delivery system 24 can be found in co-pending, commonly owned United States Patent Application Serial No. 11/255,116, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which is incorporated herein by reference.

2. Endovascular Stapling System

The endovascular stapling system 16 comprises a steerable endovascular guide system 30 comprising a first steerable guide 30A and a second steerable guide 30B, and a companion obturator 32 (see Figs. 10A and 10B). The endovascular stapling system 16 also comprises a plurality of endovascular staples 36 (Fig. 11A) and, desirably, a cassette 34 for holding the staples 36 (see Fig. 11B), as well as an endovascular staple applier 38 (see Figs. 12A and 12B). It is to be appreciated that the steerable endovascular guide system 30 may comprise a single guide device incorporating the features of the first steerable guide 30A and the second steerable guide

30B (see Fig. 10D).

The stapling system 16 may be used to apply an apposition force to the endovascular graft 12 to modify the shape of the endovascular graft to conform to the shape of the vessel wall. The endovascular stapling system 16 is also adapted to provide apposition force for improved sealing and fixation to eliminate movement and/or migration of the endovascular graft 12 within the vascular system. The endovascular stapling system 30 and endovascular staples 36 may also be used without the use of a graft 12 to close the entrance of a vessel dissection to blood flow.

a. Steerable Endovascular Guide and Companion Obturator

Referring to Figs. 10A through 10D, the steerable endovascular guide system 30 is a single use system that is supplied with a companion obturator 32 to the user within its package 50 in a sterile condition. The steerable endovascular guide system 30 is sized and configured to direct the endovascular staple applier 38 through at least one or more resolved angles to the desired location in a vessel for implantation of one or more endovascular staples 36, i.e., through one or more steerable segments 167A and 167B. In one embodiment shown in Figs. 10A and 10B, steerable segment 167A is a component of the first steerable guide 30A, and steerable segment 167B is a component of the second steerable guide 30B.

In an additional embodiment shown in Fig. 10D, steerable segment 167A and steerable segment 167B are both components of an integrated endovascular guide system 30.

The first (inner) steerable endovascular guide 30A includes a guide tube 164A, and a handle 166A coupled to the proximal end of the guide tube 164A. The guide tube

164A defines an open interior lumen 168A accommodating passage of the endovascular staple applier 38 (during use).

The second (outer) steerable endovascular guide 30B is similar to the first steerable guide 30A, except the second steerable guide tube 164B has a shorter overall length, as will be described below. The second steerable guide 30B includes a guide tube 164B, and a handle 166B coupled to the proximal end of the guide tube 164B. The guide tube 164B defines an open interior lumen 168B accommodating passage of the obturator 32 (during deployment) and the guide tube 164A of the first steerable endovascular guide segment 30A (during use).

The distal portion of the two segment steerable endovascular guide system 30 can be deflected in one or more distinct segments comprising the first steerable segment 167A and the second steerable segment 167B (as shown in phantom lines in Figs. 10A and 10B), and re-straightened by deflection means, such as steering wires or pull cords (not shown) coupled to a first rotational deflector knob 170A on the handle 166A of the first steerable guide 30A for control of the first segment 167A, and a second deflector knob 170B on the handle 166B of the second steerable guide 30B for control of the second segment 167B. Each deflector knob 170A, 170B is adapted to move its respective steerable segment 167A, 167B, from a first, generally straight position for deployment to the general targeted region, to a second, articulated position for alignment of the distal end of the guide tube 164A, and the staple applier 38, to be in contact with the vessel wall for staple deployment.

In the two component configuration, the guide tube 164A of the first steerable endovascular guide 30A is inserted (i.e., nested) into the lumen 168B of the guide tube 164B of the second steerable guide 30B until the

distal end of the handle 166A is positioned near or against the proximal end of the handle 166B. The length of the second guide tube 164B is less than the length of the first guide tube 164A (see Fig. 10B). This allows the distal end segment 167A to be independently articulated (via the rotational deflector knob 170A) as it may not be confined within the second guide tube 164B. In addition, the first steerable guide 30A may be selectively moved longitudinally relative to the second steerable guide 30B. Longitudinal adjustment of the first steerable guide 30A allows the length of the distal end segment 176A to be adjusted. Because the first guide tube 164A passes through and extends beyond the distal end of the second guide tube 164B, when the distal end segment 167B of the second guide tube 164B is articulated (via the rotational deflector knob 170B), the first guide tube 164A articulates with the second guide tube 164B. The nested guide tubes 164A and 164B allow for distal end segments 167A and 167B to be independently steerable and longitudinally adjustable to produce at least one resolved angle to aid in positioning the stapler applier 38 in a desired location to produce a force resolution desired to deploy a staple 36.

In a representative embodiment, the over-all length of guide tube 164A, not including handle 166A, is preferably between 40 and 120 cm and most preferably between 60 and 110 cm, and the length of the two segment deflectable tip is preferably between 1.0 and 10 cm and most preferably between 2 and 5 cm. The first segment 167A is preferably between about 1.0 and 5.0 cm, and the second segment 167B is preferably between about 1.0 and 2.5 cm. It is to be appreciated that the lengths of the segments may change depending on the body lumen in which the endovascular guide system is being used. C-shaped radiopaque markers 172A and 172B may be located at or

near the distal tip of the guide tube 164A and 164B respectively, to aid in orientation under fluoroscopy.

In yet an additional embodiment of a steerable endovascular guide shown in Fig. 10E, the steerable guide 30C may include a single control handle 166C with a single steerable guide tube 164C, as compared to the steerable guides shown in Fig. 10B and 10D, where assemblies are combined to produce a steerable endovascular guide. The control handle 166C may be adapted for steering the guide tube 164C in multiple directions using, for example, a first deflector knob 170C and second deflector knob 170D. As can be seen, the single guide tube is shown with two steerable segments 167C and 167D.

In a representative embodiment, the obturator 32 is desirably sized and configured with a lumen 174 accommodating conventional over-the-wire delivery within a patient's vasculature, e.g., using an appropriately sized guide wire.

Further details of representative constructions of a steerable endovascular guide 30A can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,619, filed October 20, 2005, and entitled " Devices, Systems, and Methods for Guiding an Operative Tool into an Interior Body," and co-pending, commonly owned United States Patent Application Serial No. 11/255,116, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which are both incorporated herein by reference.

b. The Endovascular Staple and Companion Cassette

The endovascular staple 36 (see Fig. 11A) is a single use component that is supplied, desirably in a companion cassette 34, to the user within a package in a

sterile condition. The endovascular staple 36 is sized and configured to attach the endovascular graft 12 to a vessel wall, and/or to close the entrance of a vessel dissection.

In the illustrated embodiment (see Fig. 11A) the endovascular staple 36 comprises a main staple body 176 that is helical-shaped. The helical-shape allows the endovascular staple 36 to pierce and engage tissue in response to rotation of the main staple body 176, thereby securing attachment of the endovascular graft 12 to a vessel wall.

In a representative embodiment, the main staple body 176 is manufactured from medical grade wire having a diameter between about 0.1 mm and 1.0 mm. In a representative embodiment, the endovascular staple 36 is approximately between about 2 mm and 12 mm in over-all length and approximately between about 1.0 mm and 10 mm in maximum diameter. The leading end 178 of the main staple body 176 is desirably sharpened to facilitate atraumatic deployment through the graft materials and vessel wall. The proximal end 180 of the main staple body 176 is desirably closed to prevent over-penetration of the endovascular staple 36.

Desirably, a plurality of staples 36 (e.g., ten) are provided in a convenient cassette 34 (see Fig. 11B), to allow easy and accurate loading into the endovascular staple applier 38. The cassette 34 includes a base 208 having a plurality of foil covered spaced apart staple ports or stations 210, each sized to house a staple 36. A deformable cover 212 (e.g. a foil cover) may be positioned over each staple port 210, and may include a precut shape, such as an "X". The precut "X" allows access for the staple applier 38 to the staple 36 within the port 210, and when the staple applier is inserted the deformable cover 212 and associate "X" deform 213,

providing a visual indication to the user which port has been accessed. In use, an operator identifies a port 210 having a precut "X" in the cover 212. The operator operates the staple applier 38 to load the staple 36 from the foil covered port 210, as will be described in greater detail below. After implanting the withdrawn staple 36, the operator again identifies a port 210 having a precut "X" in the cover 212. The operator again operates the staple applier 38 to load the staple 36 from the foil covered port 210 for implantation. In this way, the cassette 34 aids the operator in loading individual staples on the staple applier 36 for implantation in a single fire (one at a time) fashion.

Further details of representative constructions of an endovascular staple 36 and companion cassette 34 can be found in co-pending, commonly owned United States Patent Application Serial No. 11/255,116, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which is incorporated herein by reference.

c. Endovascular Staple Applier

(1) Overview

The endovascular staple applier 38 (see Figs. 12A and 12B) is a single use component that is supplied to the user within a package 48 in a sterile condition. In the illustrated embodiment, the endovascular staple applier 38, a supply of endovascular staples 36, and the staple cassette 34 are provided, for the sake of convenience, in a single package 48. The endovascular staple applier 38 is sized and configured to pass through the lumen 168A of the first steerable endovascular guide 30A guide tube 164A, which may be nested within the lumen 168B of the second steerable endovascular guide 30B guide tube 164B and to be selectively operated to implant one or more endovascular staples 36 through the graft (when

used) and into the vessel wall.

In the illustrated embodiment, the endovascular staple applier 38 comprises an applier catheter 182 and a control handle 184 coupled to the proximal end of the applier catheter 182. The applier catheter 182 carries a rotationally driven member 186 at its distal end. A battery powered motor 188 enclosed within the handle 184 is coupled to the driven member 186, to selectively rotate the driven member 186 either in a forward (e.g., clockwise) direction and reverse (e.g., counterclockwise) direction. A control circuit 190 in the handle 184 is coupled to the motor 188 and to a forward control button 192 and a reverse control button 194 on the handle. The control circuit 190 governs operation of the motor 188 according to pre-programmed operating parameters in response to user commands received by manipulation of the buttons 192 and 194.

In use, an endovascular staple 36 is loaded into the driven member 186 from the cassette 34, e.g., by placing the distal end of the applier catheter 182 into an exposed staple port 210 in the cassette 34 and pressing the reverse control button 194 (see Fig. 12C). The now loaded endovascular staple applier catheter 182 is passed through the nested guide tubes 164A and 164B of the endovascular guide system 30, which has been manipulated beforehand to be at an intended implantation site for the endovascular staple 36 (see Figs. 13A to 13C). To simplify Figs. 13A to 13C, the delivery system 24 is not shown.

As can be seen in Fig. 13A, the nested guide tubes 164A and 164B are adapted to guide the staple applier catheter 182 through one or more steerable segments 167A and 167B to the desired location in a vessel for implantation of one or more endovascular staples 36. The steerable guide system 30 may be used to apply the

desired resolution of force to the endovascular graft 12 to modify the shape or form of the endovascular graft to conform to the shape of the vessel wall. This resolution of force can be utilized to deflect a portion or portions of the endovascular graft against the vessel wall to implant a staple 36.

Once the endovascular staple applier catheter 182, loaded with a staple 36, is positioned at the desired location and the resolution of force is achieved, the physician presses the forward control button 192 to command rotation of the endovascular staple 36 in the forward direction, i.e., into tissue (see Fig. 13B).

The control circuit 190 is desirably pre-programmed to require a two-stage implantation process. The first stage commands only a partial implantation of the staple 36. In the first stage, the physician is allowed to ascertain whether the staple 36 is placed correctly at the desired location and that the desired located is suitable for implantation of the staple 36. While in the first stage, the physician is allowed to retract the staple 36 (by pressing the reverse control button 194) and to re-position the staple 36.

The control circuit 190 commands a full final deployment of the staple 36 only after a deliberate entry of the second stage. In the first and second stages, the control circuit 190 generates audible tones and/or visual indicators (e.g., blinking lights) during operation of the motor 188, to indicate the position of the staple and available direction of motion.

Once the staple 36 is implanted, the endovascular staple applier 38 is withdrawn through the nested guide tubes 164A and 164B. The physician identifies another port 210 having a precut "X" in the cover 212. The staple applier 38 is reloaded. The two segment endovascular guide system 30 is manipulated to another desired

implantation site, and the endovascular staple applier 38 (reloaded with another staple 36) is redeployed and operated in the manner just described (see Fig. 12C). The endovascular staple applier 38 is intended to be loaded, deployed, and reloaded in this way multiple times for a single patient.

Further details of representative constructions of an endovascular staple applier 38 and methods of its use can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,950, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including the Use of a Fastening Tool" which is incorporated herein by reference.

(2) Tracking the Relative Position of the Endovascular Staple Applier in the Endovascular Guide

As seen in Fig. 14A, the endovascular staple applier 38 desirably includes indicia 196, which is visible to a naked eye (i.e., without resort to fluoroscopic visualization or other visualization techniques that augment human vision) that indicates the extent to which the driven distal end 186 of the applier catheter 182, which carries the endovascular staple 36, resides within the guide tube 164A of the first steerable endovascular guide 30A. In particular, the visible indicia 196 indicates when the driven distal end 186 of the applier catheter 182 and the staple 36 it carries have arrived at a predetermined location within the guide tube 164A near to the distal end of the guide tube 164A. In this way (see Figs. 14B and 14C), the physician can quickly and accurately ascertain, without resort to fluoroscopic visualization, that the distal end 186 of the applier catheter 182, and the endovascular staple 36 it carries,

are positioned adjacent the end of the guide tube 164A, ready for final deployment, once the guide tube 164A is placed at the intended implantation site. The visible indicia 196 can also indicate the extent to which the driven distal end 186 of the applier catheter 182 has been extended outside the distal end of the guide tube 164A.

In the illustrated embodiment (see Fig. 14A), the indicia 196 comprises visible material or markings M on the most proximal section of the applier catheter 182, adjacent the handle 184, that is marked or colored differently or is otherwise differentiated from the remainder of the applier catheter 182. In a representative example, a prescribed length of contrast-colored tubing 198 can be placed at the most proximal end of the applier catheter 182, where it exits the handle 184.

The contrast-color tubing 198 has a prescribed length. The distal end of the tubing 198 marks a line of differentiation between the tubing 198 and the remainder of the applier catheter 182. The length is selected so that the distal end of the tubing 198 registers with the insertion port/hemostatic seal 200 on the handle 166A of the first steerable endovascular guide 30A (see Fig. 14B) when the driven distal end 186 of applier catheter 182 rests at a desired inset distance d within the distal end of the guide tube 164A (see Fig. 14C).

In this way, the indicia 196 indicates when the applier catheter 182 has reached a desired location relative to the end of the guide tube 164A, and is ready to be further advanced to implant the endovascular staple 36. The contrast-color tubing 198 may further include additional markings M along its length by which the physician can gauge advancement of the applier catheter 182 beyond the guide tube 164A.

The indicia 196 makes it possible for the physician, without resort to fluoroscopic visualization, to always know the position of the endovascular staple 36 and staple applier 182 relative to the end of the endovascular guide system 30 (e.g., within or outside the guide tube 164A.

(3) The Motor Control Circuit

In a representative embodiment (see Figs. 15A and 15B), the control circuit 190 for the motor includes an optical encoder 250 coupled to a counting function 252, to enable counting the revolutions of the battery powered motor 188. The control circuit 190 also includes a sensing function 254 that senses the magnitude of current being drawn by the motor 188, for deriving torque that the motor 188 is encountering. The control circuit 190 also includes a comparison function 256 that compares the magnitude of the sensed torque (current) with set torque limits in either the forward or reverse direction, to change the state of operation should excess torque conditions be encountered.

The control circuit 190 carries embedded code, which expresses pre-programmed rules or algorithms under which different operation states are entered and motor command signals are generated in response to input from the external control sources and the counting, sensing, and comparison functions. The pre-programmed rules or algorithms of the control circuit 190 are designed to conserve power consumption, placing the circuit into a standby (wait) mode between staple loading and deployment cycles. This makes it possible to power up the staple applier just once and to leave the staple applier on during an entire procedure, avoiding time consumed in repeated power ups and power downs. The pre-programmed rules or algorithms of the control circuit also dictate that a desired sequence of steps is faithfully followed

in loading, deploying, and reloading the staples, prompting the physician at the initiation of each step and not allowing any short-cuts or deviations along the way.

Further details of representative constructions of an endovascular staple applier 38 and methods of its use, including features of the pre-programmed rules or algorithms of a representative control circuit 190, can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,950, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including the Use of a Fastening Tool" and co-pending, commonly owned United States Patent Application Serial No. 11/488,305, filed July 18, 2006, and entitled "Endovascular Aneurysm Devices, Systems, and Methods", which are both incorporated herein by reference.

C. The Instructions for Use, Including Deploying an Endovascular Graft

The instructions for use 58 can direct use of catheter-based technology via a peripheral intravascular access site, such as in the femoral artery, optionally with the assistance of image guidance. Image guidance includes but is not limited to fluoroscopy, ultrasound, magnetic resonance, computed tomography, or combinations thereof. The instructions for use may include instructions for implanting an endovascular graft 12 to repair an aortic aneurysm, for example. The instructions for use may also include instructions for implanting endovascular staples 36 without the use of a graft 12, for the repair of an aortic dissection, for example, as will be described below.

Figs. 16A through 18B show representative embodiments of the steps that representative instructions for use 58 can incorporate or direct.

In a representative embodiment, the instructions for use 58 may include the achievement of percutaneous vascular access by conventional methods into the femoral artery, for example. In this arrangement, the patient is placed on an imaging table, allowing fluoroscopic visualization from the aortic arch to the femoral artery bifurcations. Access is secured to one or both contralateral and ipsilateral branches by standard techniques using introducer sheaths (which can be supplied as part of the kit 40). Using fluoroscopic guidance, access to the patient's aortic arch can be achieved with an appropriately sized guide wire through one or both femoral access sites.

1. Position the Endovascular Graft in the Targeted Endovascular Treatment Site

In this arrangement, the instructions 58 for use may include positioning of the endovascular graft 12 to be deployed. An unsupported graft, and a delivery system 24 including stabilizing arms 106 are shown. It is to be appreciated that other configurations of grafts 12, and delivery systems 24, i.e., without stabilization arms, both as previously described, may be used and are intended to be included in the scope of the invention. It is also to be appreciated that at anytime during or after the retraction of the graft retention jacket, the entire graft assembly may be repositioned within the vasculature. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include, but are not limited to:

(i) after flushing the delivery system 24 with heparinized saline, positioning the delivery system 24 within an aortic abnormality over the guide wire via a femoral access site, which has been previously established in conventional fashion (Fig. 16A);

(ii) visualizing the proper position and orientation of the endovascular graft 12 using the radiopaque markers (e.g., proximal stent markers 78, distal stent markers 80 and the marker(s) 120 positioned at or near the leading edge of the graft retention jacket 102;)

(iii) withdrawing the graft retention jacket 102 of the delivery system 24 by rotating the jacket retraction knob 124 and/or sliding the jacket retraction slide 126 away from the patient. Alternatively, the mechanical advantage mechanism may be terminated by the physician at any point during the jacket retraction. The instructions may note that the proximal portion 65 of the endovascular graft 12 will not open during retraction of the jacket 102 and that the proximal portion 65 and distal portion 66 of the graft remain collapsed and connected to the delivery system 24, and that at anytime during or after the retraction of the jacket retention jacket the entire graft assembly may be repositioned within the vasculature (Fig 16B);

(iv) verifying the position and orientation of the endovascular graft 12 using the radiopaque markers (e.g., 78, 80, and 120,); and opening the distal portion 66 by retracting the distal release slide 118. Alternatively, the distal portion 66 may open on its own, without the need to operate any controls.

(v) releasing the endovascular graft proximal portion 65 from the delivery system by retracting the proximal end release slide 114 on the handle away from the patient (Fig. 16C). When a delivery system 24 incorporating stabilizing arms 106 or other release wires are used, the instructions may note that the proximal portion (or other portions) of the endovascular graft 12 may still remain secured to the delivery system 24. The physician thereby maintains control and can manipulate the position and orientation of the graft assembly 12

during deployment of endovascular staples.

The instructions may also note that the use of release wires in place of stabilizing arms 106 may be used to attach the endovascular graft 12 to the inner assembly 100 to maintain control of the graft 12 while implantation of endovascular staples takes place.

With an alternative embodiment of a delivery system 24 without stabilizing arms, as previously described, after the proximal portion 65 and distal portion 66 are released from the delivery system, the graft 12 is free of the delivery system 24 and remains in position with the radial force of the proximal stent 70 and/or additional stents incorporated with the graft 12. It is to be appreciated that any of the delivery systems described herein may be removed at this stage of the procedure, or may be removed after endovascular staples have been deployed, as described below.

2. Deploy Endovascular Staples to Secure the Position of the Endovascular Graft

The instructions for use 58 may next instruct securing of the position of the proximal portion of the endovascular graft 12 using endovascular staples 36. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include, but are not limited to:

(i) placing an appropriate length and sized guide wire via the femoral access site into the aortic arch. The endovascular graft 12 includes distal end radiopaque markers 80 that outline the opening of the distal portion 66 of the endovascular graft 12. The guide wire is to be placed through this opening and its position verified using standard endovascular techniques;

(ii) using fluoroscopic guidance, advancing the second steerable endovascular guide 30B with the obturator 32 over the guide wire into a position within

the proximal neck of the thoracic aneurism (Fig. 16D). The C-shaped radiopaque marker 172B located at the distal tip of the guide tube 164B will aid in fluoroscopic visualization. Position the steerable endovascular guide system 30 at the desired location for endovascular staple implantation within a desired location on the endovascular graft 12, (e.g., between the marker bands 78 on the proximal stent 70 and the bottom edge of the proximal stent 70.) In addition, the steerable endovascular guide system 30 may be used to contact and apply an apposition force to deflect a portion or portions of the proximal portion, or other portions of, the graft 12 and/or the stent 70 against the vessel wall to conform the shape of the endovascular graft 12 to the vessel wall at the desired location;

(iii) removing the guide wire and obturator 32 to open the lumen 168B of the second steerable endovascular guide 30B and inserting the guide tube 164A of the first steerable endovascular guide 30A into the lumen 168B. (Alternatively, the first steerable endovascular guide 30A and the second steerable endovascular guide 30B may be inserted at the same time with only one obturator in the lumen 168B of the second steerable endovascular guide 30B.)

(iv) deflecting the distal segments 167A and/or 167B of the two segment steerable endovascular guide system 30 toward the first intended staple implantation area by rotating the first and/or second deflector knobs 170A, 170B to achieve one or more bends or angles, while observing with fluoroscopic guidance. The instructions may note that the C-shaped fluoroscopic markers 172A and 172B will appear as a straight line when their respective catheters are oriented laterally, as a right curve "(" when oriented anteriorly, and as a left curve ")" when oriented posteriorly. Alternatively, the manipulation of

the guide system (deflecting the distal segments) can be performed after the insertion of the endovascular staple applier;

(v) turning on the endovascular staple applier 38 by pressing one or more of the control buttons 194, 192 for a predetermined amount of time. This can initiate a self-checking sequence with audible and/or visual indicators. At the end of this sequence, the reverse indicator 202 will indicate that the endovascular staple applier 38 is ready to load the first endovascular staple 36. The instructions may note that, if at the end of the self check sequence, the error light 204 is illuminated, the endovascular staple applier 38 has encountered an error. The error can be cleared by pressing one or more of the control buttons 194,192 for a predetermined amount of time. After the error has been cleared, the self check sequence will initiate. If the error light 202 can not be cleared the endovascular staple applier 38 is not functional and should not be used;

(vi) load the staple by pressing the reverse command button 194 on the handle. While the motor 188 is running, insert the distal end of the endovascular staple applier catheter 182 into a port 210 having a precut "X" in the cover 212 of the cassette 34. The reverse indicator 202 will illuminate, and the endovascular staple will be drawn from the cassette into the distal end of the staple applier 38. When the endovascular staple 36 is loaded, an audible tone (e.g., two short beeps) will be heard, and the forward indicator 206 will illuminate. This indicates that the endovascular staple 36 is now preloaded in the staple applier 38, and the applier 38 can be removed from the cassette 34. The precut "X" in the cover 212 deforms with the insertion of the staple applier 38. The instructions may urge the physician to verify that the endovascular staple 36 is in place by visually inspecting

the distal tip of the applier 38;

(vii) while stabilizing the control handle 160C or handles 166A and 166B of the endovascular guide system 30 relative to the patient, inserting the now-loaded endovascular staple applier 38 through the hemostatic seal at the proximal end of the first steerable endovascular guide control handle 166A. The instructions may direct the physician to observe the location of the visible contrast-color tubing 198 or other indicia on the proximal end of the applier catheter 182 and to halt further insertion of the staple applier 38 when the end of the contrast-color tubing 198 registers with the insertion port/hemostatic seal on the handle of the steerable endovascular guide (as shown in Fig. 14B). This indicates that the distal end of applier catheter 182 rests a desired distance from the distal end of the guide tube 164 (as shown in Fig. 14C);

(viii) under fluoroscopic guidance, advancing the endovascular staple applier 38 through the steerable endovascular guide system 30 until the endovascular staple applier 38 emerges from the distal end of the endovascular guide system 30 and contacts the endovascular graft 12. Continue to advance the endovascular staple applier 38 until resistance is felt and/or visual indication of apposition can be seen using fluoroscopy. This indicates that the endovascular staple applier 38 is in apposition against the endovascular graft 12 and against the vessel wall at the desired location for staple deployment, and that the nested first and second steerable endovascular guide tubes 164A and 164B are fully or partially resolving the generally opposite apposition force. This resolution of force can be applied with either the staple applier 38 or endovascular guide system 30 alone, or in combination to deflect a portion or portions of the proximal portion, or

other portions of the graft 12 and/or stent 70 against the vessel wall to conform the shape of the endovascular graft 12 to the vessel wall at the desired location.

(ix) using the control handle 184 of the endovascular staple applier 38, pressing the forward control button 192 for achieving the first stage of endovascular staple deployment. The endovascular staple will partially deploy and pause. An audible tone may be heard (e.g., four beeps) and the forward and reverse indicator 202 and 206 will illuminate (e.g., alternatively blink), indicating that the operator may continue deployment or withdraw the endovascular staple 36 back into the applier 38. The instructions may note that, in the event of a power loss when the staple 36 is partially deployed, the staple may be removed manually, for example, by manually rotating the handle 184 and catheter 182 in a counter-clockwise direction until the staple 36 disengages from the graft and tissue. The staple applier 38 can be removed from the endovascular guide 30 in this condition;

(x) if the endovascular staple 36 is not in the desired location, pressing the reverse control button 194 re-houses the staple 36 inside the staple applier 38 for re-positioning;

(xi) if the endovascular staple 36 is in the desired position, completing the final stage of staple deployment by pressing the forward control button 192 to implant the endovascular staple 36 through the graft materials and into the vessel wall (Fig. 16E). When complete, an audible tone (e.g., three beeps) is heard and the reverse indicator 202 will illuminate; Fig. 16F shows an alternative configuration of the final stage of staple deployment, similar to Fig. 16E, except that an alternative deployment system 24 without stabilizing arms has been previously removed prior to the deployment of

endovascular staples 36.

(xii) remove the endovascular staple applier 38, leaving the steerable endovascular guide system 30 in place;

(xiii) as needed, the steerable endovascular guide and/or the staple applier can be flushed with heparinized saline to prevent clotting in the lumens;

(xiv) identifying a port 210 having a precut "X" in the cover 212 to locate the next available endovascular staple port. Load the next endovascular staple in the manner described above;

(xv) repositioning the steerable endovascular guide system 30 to the next desired implantation site for an endovascular staple 36. Desirably, the physician straightens the first segment 167A and second segment 167B of the steerable endovascular guide system 30 between rotating in within the endovascular graft 12, to prevent accidental dislodgment or movement of the graft assembly 12;

(xvi) deploying the next endovascular staple 36 through the steerable endovascular guide 30 in the manner described above. Typically, 4 to 6 endovascular staples, evenly distributed about the circumference of the endovascular graft 12, will serve to secure the position of the graft 12 within the vessel (see Fig. 16G). Fig. 16H shows an alternative placement of the endovascular graft 12. As can be seen, the endovascular graft 12 incorporates an open graft portion 67 and is positioned more proximal within the aortic arch, proximal to the left subclavian artery. This position - proximal to the left subclavian artery - may be necessary in anatomies where the diseased tissue is so extensive that there is insufficient healthy tissue distal to the left subclavian artery to provide a sufficient landing zone for one or more staples 36. In prior systems where there was

insufficient healthy tissue distal to the left subclavian artery necessary to provide a sufficient landing zone for barbs or hooks, the left subclavian artery was sacrificed, and then grafted to the left common carotid artery. The present systems and methods overcome this problem with the use of the open graft section 12 that maintains a fluid flow communication path to the left subclavian artery, and the ability to secure and seal the endovascular graft 12 in this tortuous location.

(xii) after deployment of the last endovascular staple, removing the endovascular stapler applier 38 from the steerable endovascular guide system 30;

(xiii) removing the steerable endovascular guide system 30 by first re-advancing the obturator 32 and guide wire (if appropriate) into the steerable endovascular guide system 30.

3. Complete the Endovascular Graft Deployment

The instructions for use 58 may next include the completion of the deployment of the endovascular graft 12, which may (or may not) remain in a secured but partially deployed condition during the deployment of the endovascular staples, as above described. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include, but are not limited to:

(i) moving to the femoral access site, where the delivery system 24 resides;

(ii) releasing the stabilizing arms 106 or other release wires from the graft by retracting the graft release slide 116 on the handle of the delivery system away from the patient. The endovascular graft 12 is now fully released (Fig. 16J);

(iii) rejacketing the delivery system 24 by holding the jacket retention slide 126 and slowly retract the

delivery system 24, until the nosecone seals into the proximal end of the jacket 102;

(iv) remove the delivery system 24 from the patient, leaving the guide wire and femoral access introducer sheath in place if appropriate.

4. Completion of the Procedure

The instructions for use 58 may next include the completion of the procedure. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include, but are not limited to:

(i) performing post-implant aortic angiography to evaluate the implantation;

(ii) checking for endovascular leaks around the endovascular graft 12. If a leak is observed, standard endovascular techniques can be used to resolve. Additional staples may be placed, in the manner described above;

(iii) checking for proper location, blood flow, and patency of the endovascular graft 12;

(iv) removing the guide wires and femoral access sheaths and close the femoral arteriotomies according to standard practice to complete the procedure (Fig. 16K).

It is to be appreciated that the general steps just described do not necessarily need to follow the order in which they were described. It is also to be appreciated that fasteners may be applied to the distal region 66 of the endovascular graft 12 as well (as can be seen in Fig. 16K).

D. The Instructions for Use, Without Deploying an Endovascular Graft

Figs. 17A through 17C show a representative embodiment of the steps that a representative instructions for use 58 can incorporate or direct, without deploying an endovascular graft 12.

1. Deploy Endovascular Staples to Close an Aortic Dissection

In a representative embodiment, the instructions for use 58 may include the achievement of percutaneous vascular access by conventional methods into the femoral artery, for example. In this arrangement, the patient is placed on an imaging table, allowing fluoroscopic visualization from the aortic arch to the femoral artery bifurcations. Access may be secured to one or both contralateral and ipsilateral branches by standard techniques using introducer sheaths (which can be supplied as part of the kit 40). Using fluoroscopic guidance, access to the patient's aortic arch can be achieved with an appropriately sized guide wire through one or both femoral access sites.

These steps may include, but are not limited to:

(i) placing an appropriate length and sized guide wire via the femoral access site into the aortic arch.

(ii) using fluoroscopic guidance, advancing the second steerable endovascular guide 30B with the obturator 32 over the guide wire into a position at or near the tear in the aortic wall (Fig. 17A). The C-shaped radiopaque marker 172B located at the distal tip of the guide tube 164B will aid in fluoroscopic visualization. Position the steerable endovascular guide system 30 at the desired location for endovascular staple implantation within a desired stapling zone on the aortic dissection. In addition, the steerable endovascular guide system 30 may be used to contact the vessel wall and apply an apposition force desired for staple deployment. The instructions may note that the endovascular staples should be evenly distributed around the tear of the vessel wall in order to close the entrance of the dissection to blood flow;

(iii) removing the guide wire and obturator 32 to

open the lumen 168B of the second steerable endovascular guide 30B and inserting the guide tube 164A of the first steerable endovascular guide 30A into the lumen 168B. (Alternatively, the first steerable endovascular guide 30A and the second steerable endovascular guide 30B may be inserted at the same time with only one obturator in the lumen 168B of the second steerable endovascular guide 30B.)

(iv) deflecting the distal segments 167A and/or 167B of the two segment steerable endovascular guide system 30 toward the first intended staple implantation area by rotating the first and/or second deflector knobs 170A, 170B to achieve one or more bends or angles, while observing with fluoroscopic guidance. The instructions may note that the C-shaped fluoroscopic markers 172A and 172B will appear as a straight line when their respective catheters are oriented laterally, as a right curve "(" when oriented anteriorly, and as a left curve ")" when oriented posteriorly. Alternatively, the manipulation of the guide system (deflecting the distal segments) can be performed after the insertion of the endovascular staple applier;

(v) turning on the endovascular staple applier 38 by pressing one or more of the control buttons 194, 192 for a predetermined amount of time. This can initiate a self-checking sequence with audible and/or visual indicators. At the end of this sequence, the reverse indicator 202 will indicate that the endovascular staple applier 38 is ready to load the first endovascular staple 36. The instructions may note that, if at the end of the self check sequence, the error light 204 is illuminated, the endovascular staple applier 38 has encountered an error. The error can be cleared by pressing one or more of the control buttons 194,192 for a predetermined amount of time. After the error has been cleared, the self check

sequence will initiate. If the error light 202 can not be cleared the endovascular staple applier 38 is not functional and should not be used;

(vi) load the staple by pressing the reverse command button 194 on the handle. While the motor 188 is running, insert the distal end of the endovascular staple applier catheter 182 into a port 210 having a precut "X" in the cover 212 of the cassette 34. The reverse indicator 202 will illuminate, and the endovascular staple will be drawn from the cassette into the distal end of the staple applier 38. When the endovascular staple 36 is loaded, an audible tone (e.g., two short beeps) will be heard, and the forward indicator 206 will illuminate. This indicates that the endovascular staple 36 is now preloaded in the staple applier 38, and the applier 38 can be removed from the cassette 34. The precut "X" in the cover 212 deforms with the insertion of the staple applier 38. The instructions may urge the physician to verify that the endovascular staple 36 is in place by visually inspecting the distal tip of the applier 38;

(vii) while stabilizing the control handle 160C or handles 166A and 166B of the endovascular guide system 30 relative to the patient, inserting the now-loaded endovascular staple applier 38 through the hemostatic seal at the proximal end of the first steerable endovascular guide control handle 166A. The instructions may direct the physician to observe the location of the visible contrast-color tubing 198 or other indicia on the proximal end of the applier catheter 182 and to halt further insertion of the staple applier 38 when the end of the contrast-color tubing 198 registers with the insertion port/hemostatic seal on the handle of the steerable endovascular guide (as shown in Fig. 14B). This indicates that the distal end of applier catheter 182 rests a desired distance from the distal end of the guide

tube 164 (as shown in Fig. 14C);

(viii)under fluoroscopic guidance, advancing the endovascular staple applier 38 through the steerable endovascular guide system 30 until the endovascular staple applier 38 emerges from the distal end of the endovascular guide system 30 and contacts the torn vessel wall. Slowly, continue to advance the endovascular staple applier 38 until resistance is felt, and/or visual indication of apposition can be seen using fluoroscopy. This indicates that the endovascular staple applier 38 is firmly pushing against the vessel wall at the desired location for staple deployment, and that the nested first and second steerable endovascular guide tubes 164A and 164B are firmly pushing against the generally opposite vessel wall and applying the apposition force desired for staple deployment. This resolution of force can be applied with either the staple applier 38 or endovascular guide system 30 alone, or in combination to deflect a portion or portions of the vessel wall at the desired location.

(ix) using the control handle 184 of the endovascular staple applier 38, pressing the forward control button 192 for achieving the first stage of endovascular staple deployment. The endovascular staple will partially deploy and pause. An audible tone may be heard (e.g., four beeps) and the forward and reverse indicator 202 and 206 will illuminate (e.g., alternatively blink), indicating that the operator may continue deployment or withdraw the endovascular staple 36 back into the applier 38. The instructions may note that, in the event of a power loss when the staple 36 is partially deployed, the staple may be removed manually, for example, by manually rotating the handle 184 and catheter 182 in a counter-clockwise direction until the staple 36 disengages from the tissue. The staple applier

38 can be removed from the endovascular guide 30 in this condition;

(x) if the endovascular staple 36 is not in the desired location, pressing the reverse control button 194 re-houses the staple 36 inside the staple applier 38 for re-positioning;

(xi) if the endovascular staple 36 is in the desired position, completing the final stage of staple deployment by pressing the forward control button 192 to implant the endovascular staple 36 into the vessel wall (Fig. 17B). When complete, an audible tone (e.g., three beeps) is heard and the reverse indicator 202 will illuminate;

(xii) remove the endovascular staple applier 38, leaving the steerable endovascular guide system 30 in place;

(xiii) as needed, the steerable endovascular guide and/or the staple applier can be flushed with heparinized saline to prevent clotting in the lumens;

(xiv) identifying a port 210 having a precut "X" in the cover 212 to locate the next available endovascular staple port. Load the next endovascular staple in the manner described above;

(xv) repositioning the steerable endovascular guide system 30 to the next desired implantation site for an endovascular staple 36. Desirably, the physician straightens the first segment 167A and second segment 167B of the steerable endovascular guide system 30 between rotating in within the endovascular graft 12, to prevent accidental dislodgment of previously deployed staples or unnecessary contact with the vessel wall;

(xvi) deploying the next endovascular staple 36 through the steerable endovascular guide 30 in the manner described above;

(xvii) after deployment of the last endovascular staple, removing the endovascular stapler applier 38 from

the steerable endovascular guide system 30;

(xviii) removing the steerable endovascular guide system 30 by first re-advancing the obturator 32 and guide wire (if appropriate) into the steerable endovascular guide system 30.

2. Completion of the Procedure

The instructions for use 58 may next include the completion of the procedure. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include, but are not limited to:

(i) performing post-implant aortic angiography to evaluate the staple(s) implantation;

(ii) checking for endovascular leaks around the tear in the vessel wall. If a leak is observed, standard endovascular techniques can be used to resolve. Additional staples may be placed, in the manner described above;

(iii) removing the guide wire and femoral access sheath and close the femoral arteriotomies according to standard practice to complete the procedure (Fig. 17C).

It is to be appreciated that the general steps just described do not necessarily need to follow the order in which they were described.

E. Alternative Graft Configurations

The systems and methods described herein may be used to implant an endovascular graft having one or more extensions 13, as can be seen in Fig. 18A and 18B. Extensions 13 may be secured to the graft 12, or other extensions 13, using interlocking stents, for example. Or, the stapling system 16 may be used to apply a staple 36 at an overlap. The staple 36 may pierce the overlapped graft segments of graft 12 and extension 13, and further may pierce into tissue, or, the tissue may not be pierced.

Fig. 18A shows one embodiment of a graft 12 including one or more extensions 13. In this embodiment, the graft 12 may be implanted first in the desired region of the vessel. Successive extensions may then be coupled to the graft 12 and/or a previously placed extension 13. This may be repeated until the aorta is covered from the desired proximal to distal landing zones. As can be seen, the proximal portion of the distal most two extensions 13 are shown as positioned inside of the graft/extension proximal to each extension.

Fig. 18B shows an alternative embodiment where the proximal portion of the distal most two extensions 13 are shown as positioned exterior to the outer diameter of the graft/extension proximal to each extension. In this embodiment, the first distal extension 13 may be placed at or above the level of the celiac artery, for example. The column strength and/or radial expansion of the extension 13 may allow it to remain in position. One or more additional extensions 13 may be deployed further proximal to the first extension 13 with the distal portion of the second extension positioned inside of the proximal portion of the second extension 13 (or the graft 12) to extend the graft further proximal in the vessel. This may be repeated until the aorta is covered from the desired distal to proximal landing zones.

It will be appreciated that the components and/or features of the preferred embodiments described herein may be used together or separately, while the depicted methods and devices may be combined or modified in whole or in part. It is contemplated that the components of the guiding device, fastener device, and helical fastener may be alternately oriented relative to each other, for example, offset, bi-axial, etc. Further, it will be understood that the various embodiments may be used in additional procedures not described herein, such as

vascular trauma, arterial dissections, artificial heart valve attachment and attachment of other prosthetic device within the vascular system and generally within the body.

The foregoing is considered as illustrative only of the principles of the invention. Furthermore, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

We Claim:

1. A steerable guide catheter comprising:

a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool,

a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, and

a handle assembly comprising:

a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the first deflecting means adapted to bend the distal end region in a first articulated position, and

a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position.

2. A steerable guide catheter according to Claim 1:

wherein the second articulated position is different than the first articulated position.

3. A steerable guide catheter according to Claim 1:

wherein the second guide tube comprises a length that is shorter than the length of the first guide tube.

4. A steerable guide catheter according to Claim 1:

further including an operative tool that applies one or more fasteners to tissue.

5. A steerable guide catheter comprising:

a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted

for accommodating passage of an operative endovascular tool,

a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating passage of the first guide tube,

a first handle assembly comprising a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the first deflecting means adapted to bend the distal end region in a first articulated position, and

a second handle assembly comprising a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position.

6. A steerable guide catheter according to Claim 5:

wherein the second articulated position is different than the first articulated position.

7. A steerable guide catheter according to Claim 5:

wherein the second guide tube comprises a length that is shorter than the length of the first guide tube.

8. A method comprising:

providing a steerable guide catheter comprising:

a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool,

a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, and

a handle assembly comprising:

a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, and

a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position,

passing the operative tool through the guide catheter, and

operating the operative tool while residing in the guide catheter to apply at least one fastener to tissue.

9. A method according to Claim 8:

further including manipulating the first deflecting means for applying a deflecting force and bending the distal end region of the first guide tube in a first articulated position, and

manipulating the second deflecting means for applying a deflecting force and bending the distal end region of the second guide tube in a second articulated position.

10. A method according to Claim 9:

wherein the second articulated position is different than the first articulated position.

11. A method comprising:

providing a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool, the first guide tube including a first handle assembly comprising a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube,

providing a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating passage of the first guide tube, the second guide tube including a second handle assembly comprising a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube,

inserting the first guide tube into the lumen of the second guide tube,

advancing the first guide tube until the distal end region of the first guide tube extends beyond the distal end region of the second guide tube,

passing the operative tool through the guide catheter, and

operating the operative tool while residing in the guide catheter to apply at least one fastener to tissue.

12. A method according to Claim 11:

further including manipulating the first deflecting means for applying a deflecting force and bending the distal end region of the first guide tube in a first articulated position, and

manipulating the second deflecting means for applying a deflecting force and bending the distal end region of the second guide tube in a second articulated position.

13. A method according to Claim 12:

wherein the second articulated position is different than the first articulated position.

14. A steerable guide catheter system comprising:

a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool,

a second guide tube having a length and defining an

open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, and

a handle assembly comprising:

a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the first deflecting means adapted to bend the distal end region in a first articulated position,

a second deflecting means coupled to a distal end region of the second guide tube to apply a deflecting force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position, and

instructions for use describing the use of the steerable guide catheter system, the instructions comprising the operations of introducing into a vessel the steerable guide catheter, advancing the steerable guide catheter to the targeted site in the vessel, manipulating the first deflecting means for applying a deflecting force and bending the distal end region of the first guide tube in a first articulated position, and manipulating the second deflecting means for applying a deflecting force and bending the distal end region of the second guide tube in a second articulated position.

15. A system according to Claim 14:

wherein the second articulated position is different than the first articulated position.

16. A system according to Claim 14:

further including the operative tool, the operative tool adapted to apply at least one fastener to tissue while residing in the guide catheter.

17. A system according to Claim 16:

wherein the instructions for use further include instructions comprising passing the operative tool through the guide catheter, and operating the operative

tool while residing in the guide catheter to apply at least one fastener to tissue.

18. A steerable guide catheter comprising:

a first guide tube having a length and defining an open interior lumen, the first guide tube lumen adapted for accommodating passage of an operative endovascular tool, and

a handle assembly comprising:

a first deflecting means coupled to a distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the first deflecting means adapted to bend the distal end region in a first articulated position, and

a second deflecting means coupled to the distal end region of the first guide tube to apply a deflecting force to bend the distal end region of the first guide tube, the second deflecting means adapted to bend the distal end region in a second articulated position.

19. A steerable guide catheter according to Claim 18:

wherein the second articulated position is different than the first articulated position.

20. A steerable guide catheter according to Claim 18:

further including an operative tool that applies one or more fasteners to tissue.

21. A steerable guide catheter according to Claim 18:

further including a second guide tube having a length and defining an open interior lumen, the second guide tube lumen adapted for accommodating the first guide tube, and

the second deflecting means coupled to the distal end region of the second guide tube to apply a deflecting

force to bend the distal end region of the second guide tube, the second deflecting means adapted to bend the distal end region in the second articulated position.

22. A steerable guide catheter according to Claim 21:

wherein the second guide tube comprises a length that is shorter than the length of the first guide tube.

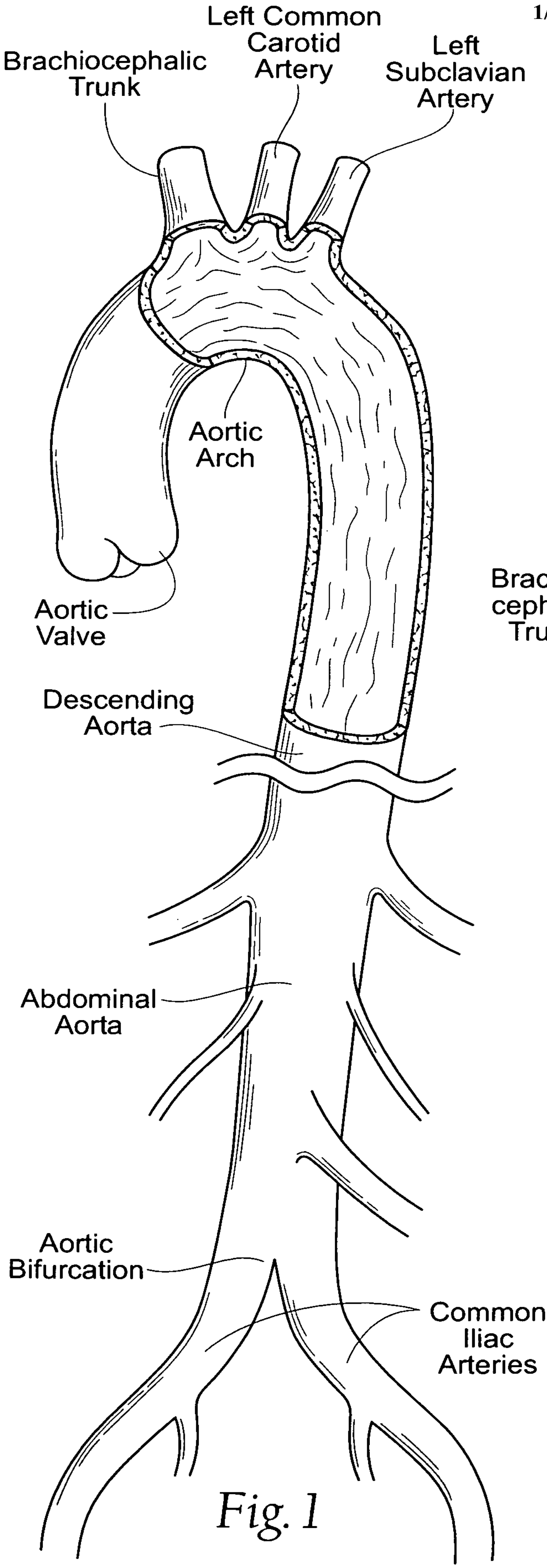

Brachiocephalic Trunk
Left Common Carotid Artery
Left Subclavian Artery
Aortic Arch
Aortic Valve
Descending Aorta
Abdominal Aorta
Aortic Bifurcation
Common Iliac Arteries

Fig. 1

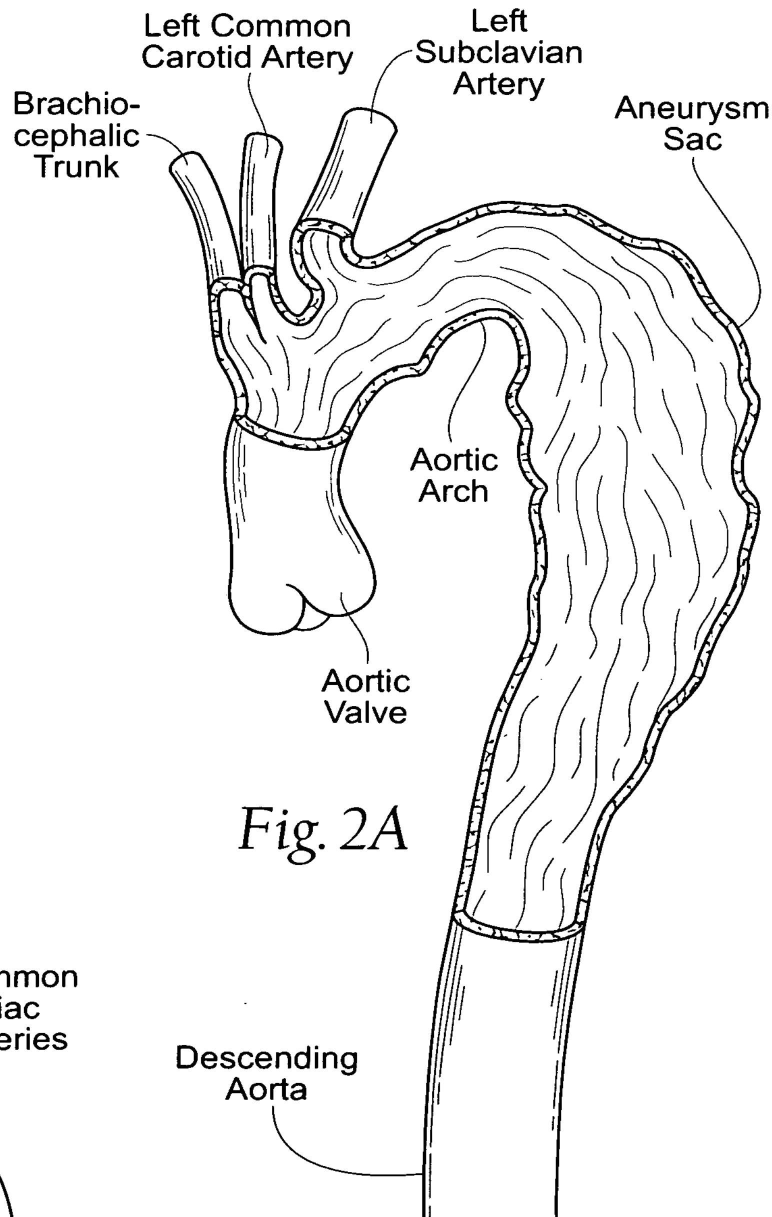

Left Common Carotid Artery
Left Subclavian Artery
Brachio-cephalic Trunk
Aneurysm Sac
Aortic Arch
Aortic Valve
Descending Aorta

Fig. 2A

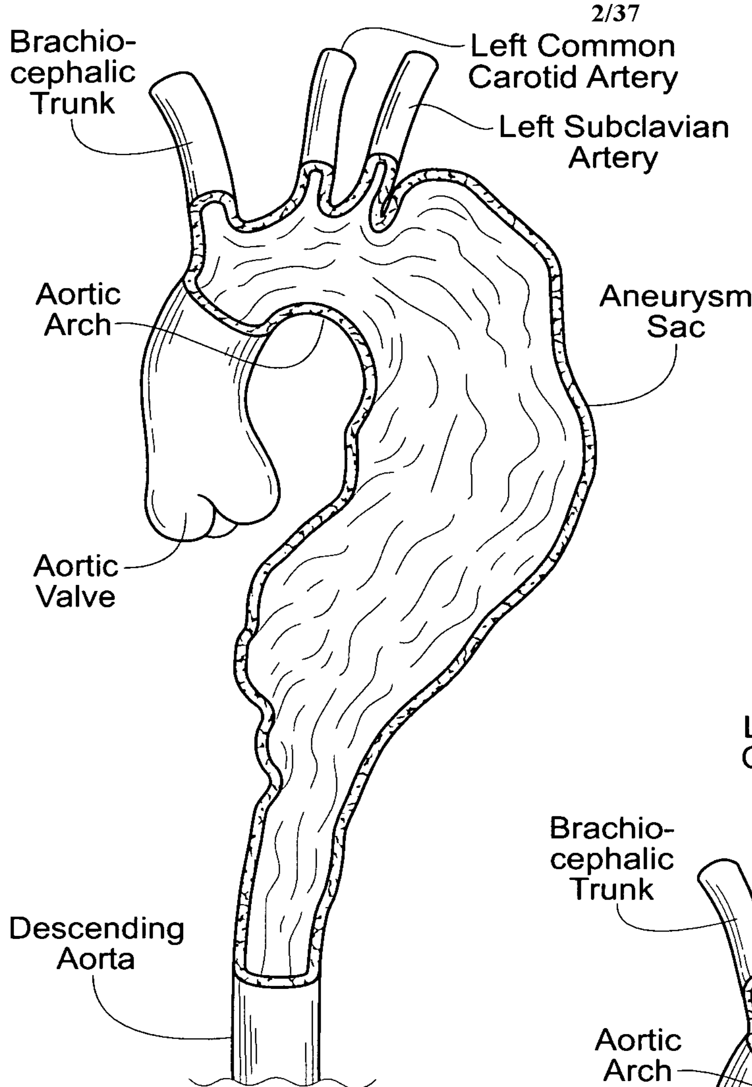

Brachio-
cephalic
Trunk
Left Common
Carotid Artery
Left Subclavian
Artery
Aortic
Arch
Aneurysm
Sac
Aortic
Valve
Descending
Aorta

Fig. 2B

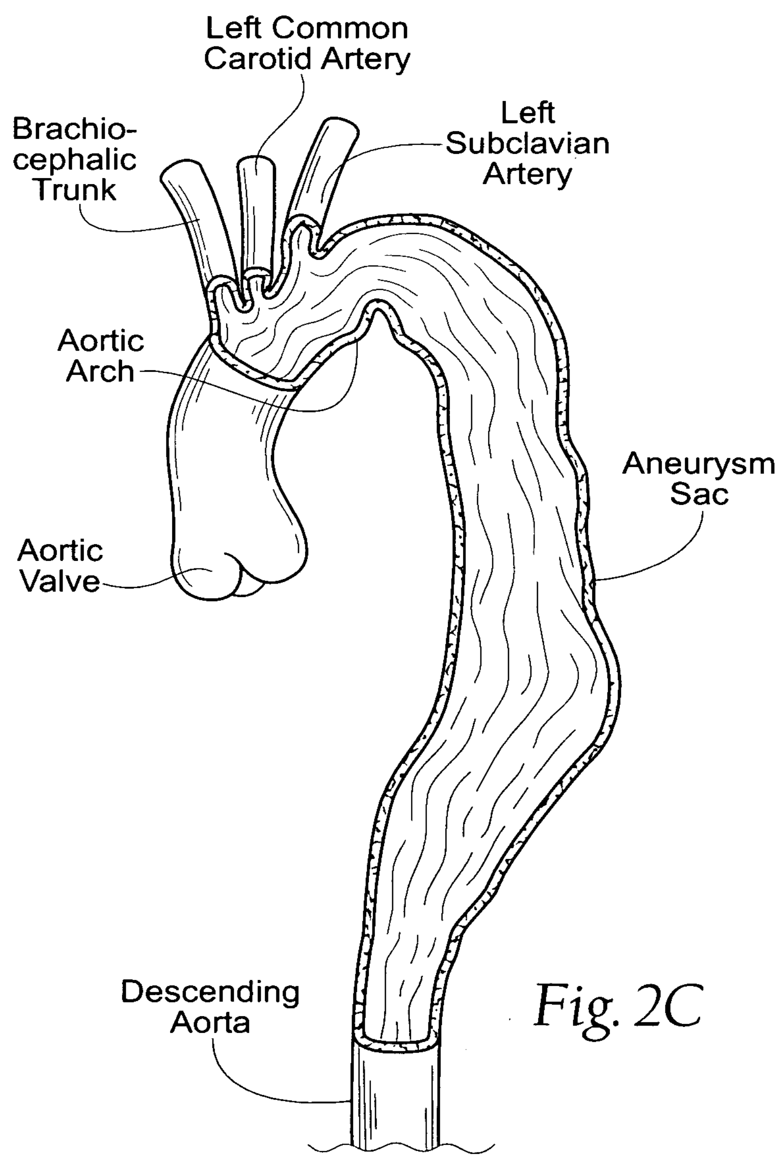

Left Common
Carotid Artery
Brachio-
cephalic
Trunk
Left
Subclavian
Artery
Aortic
Arch
Aneurysm
Sac
Aortic
Valve
Descending
Aorta

Fig. 2C

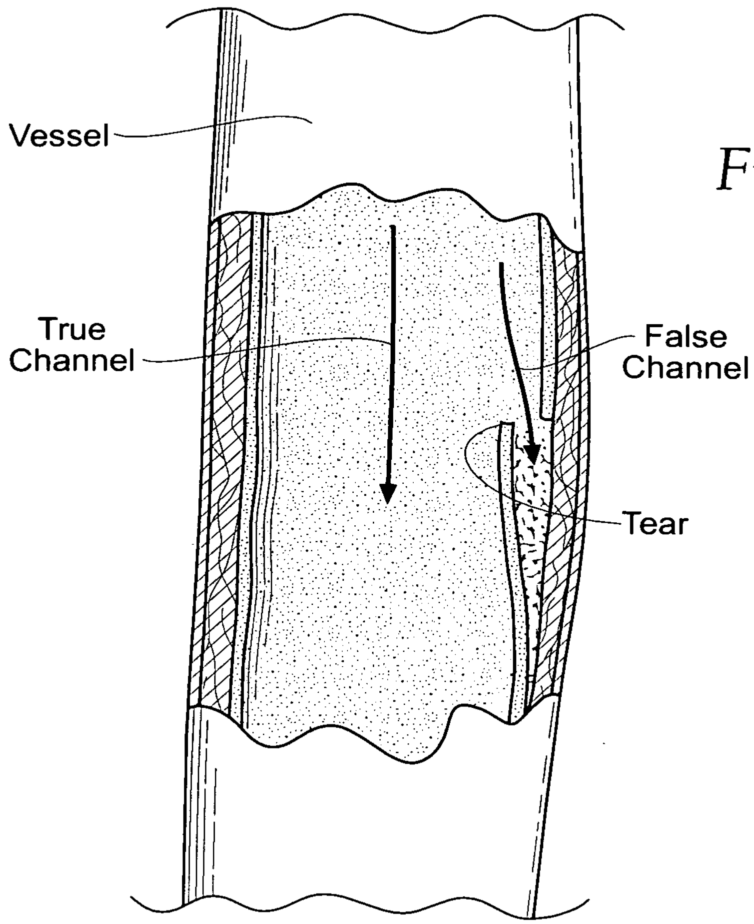

Vessel
True Channel
False Channel
Tear

Fig. 3A

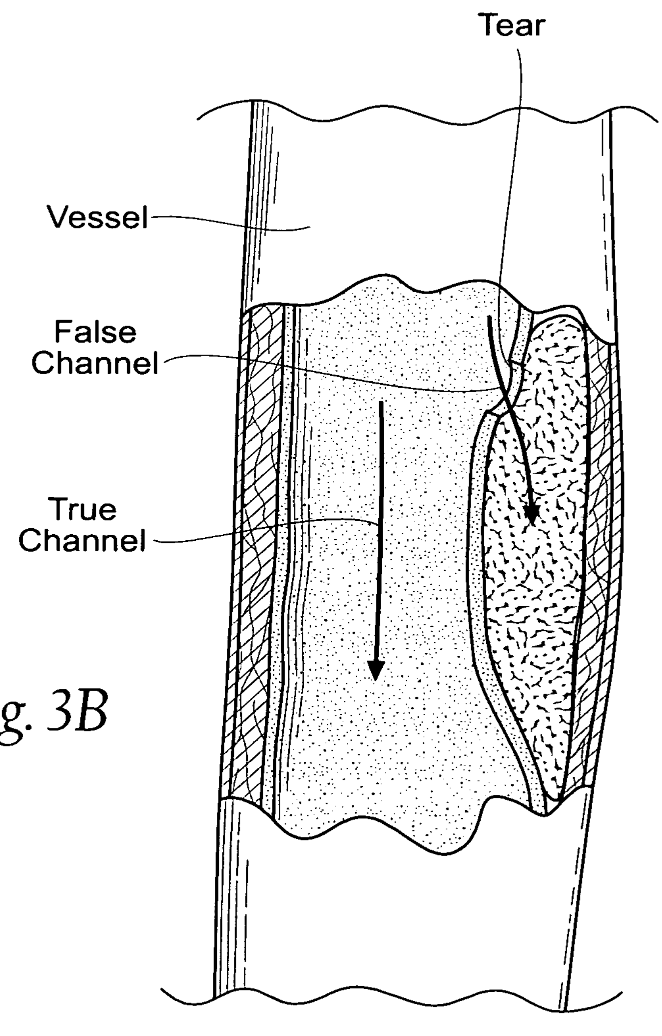

Tear
Vessel
False Channel
True Channel

Fig. 3B

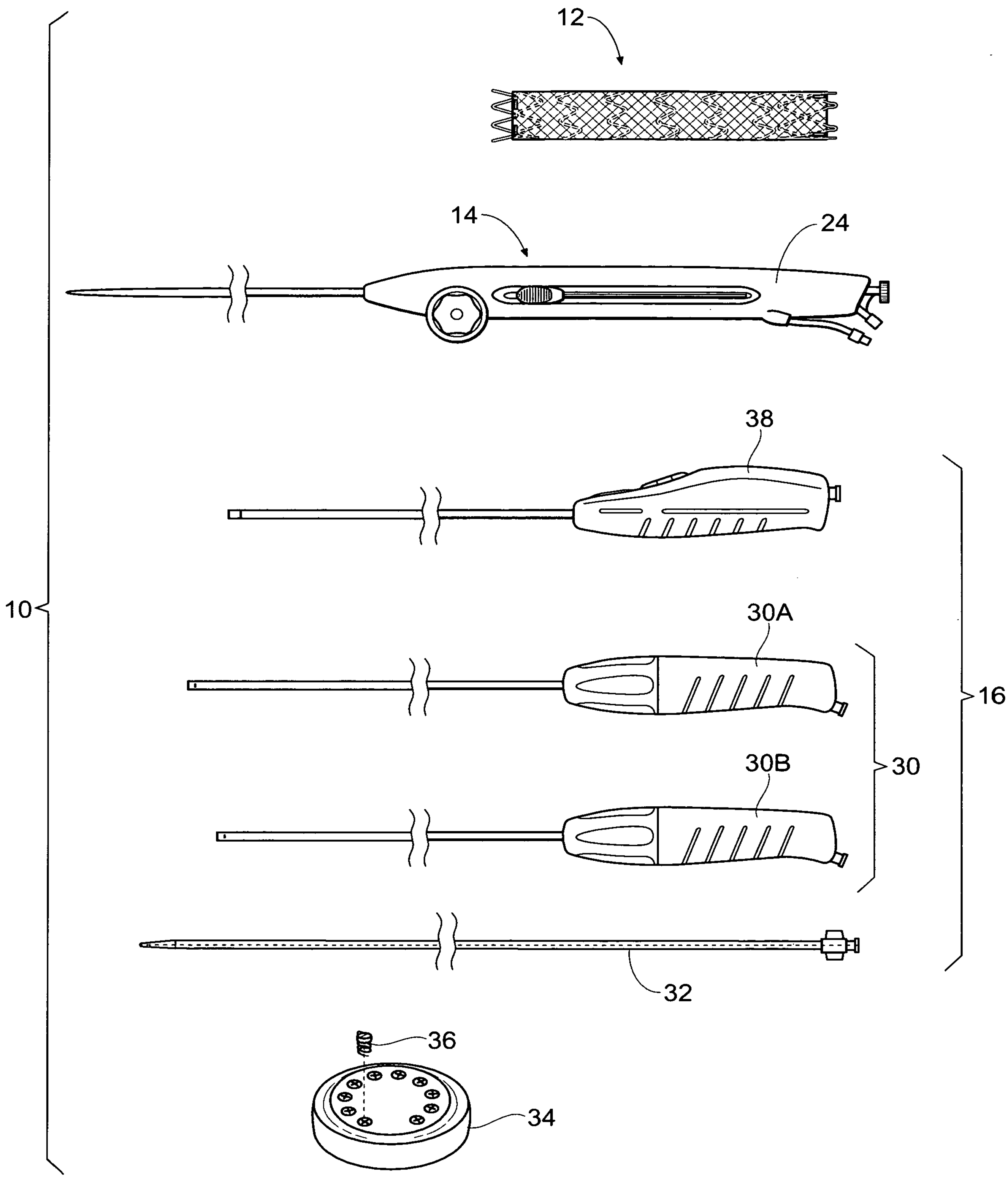
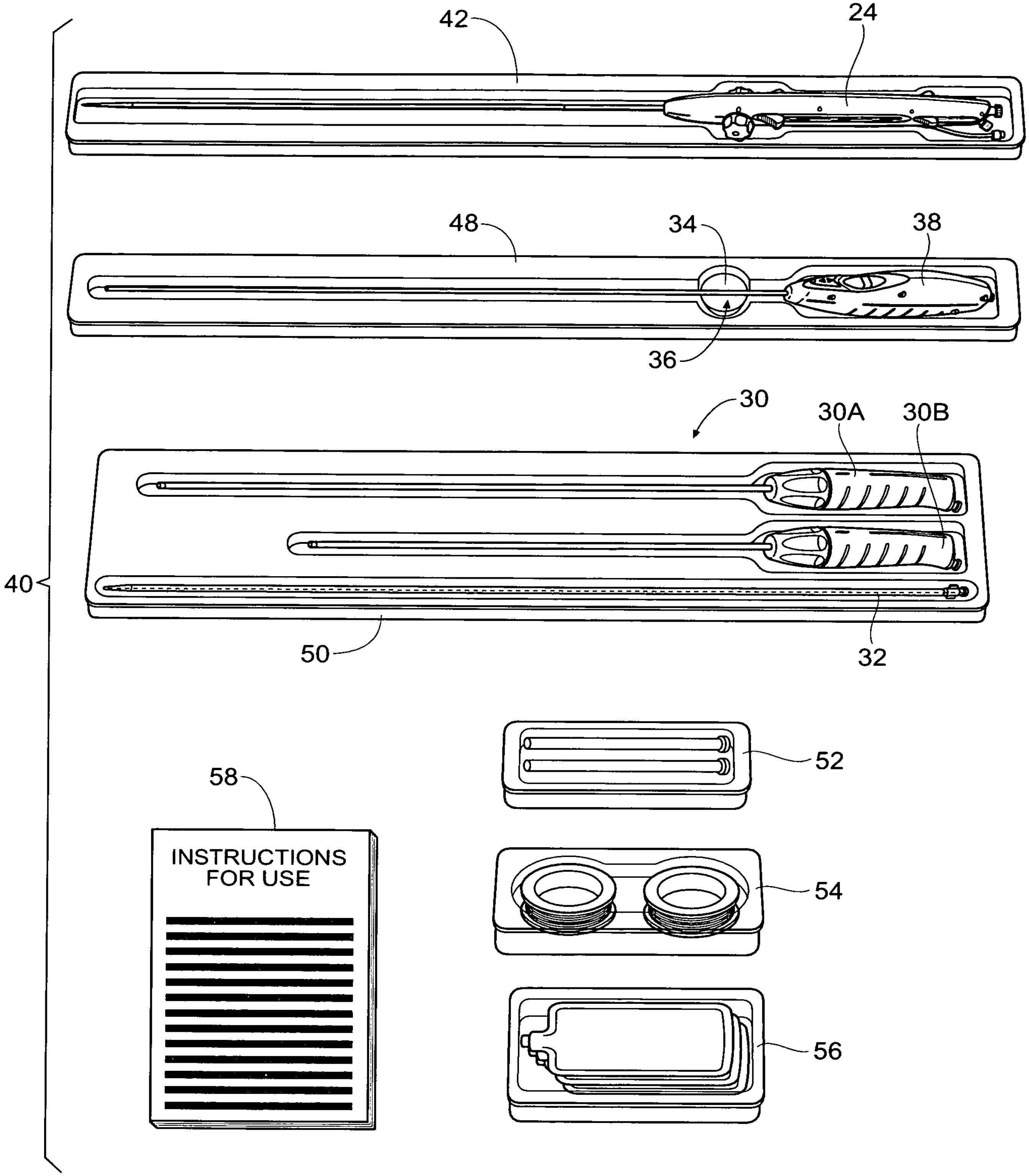


Fig. 4


42
24
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38
36
30
30A
30B
40
50
32
58
INSTRUCTIONS FOR USE
52
54
56

Fig. 5

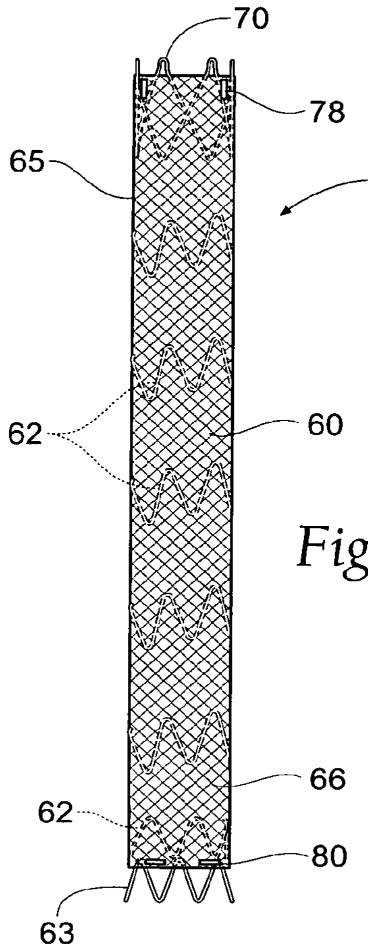


Fig. 6A

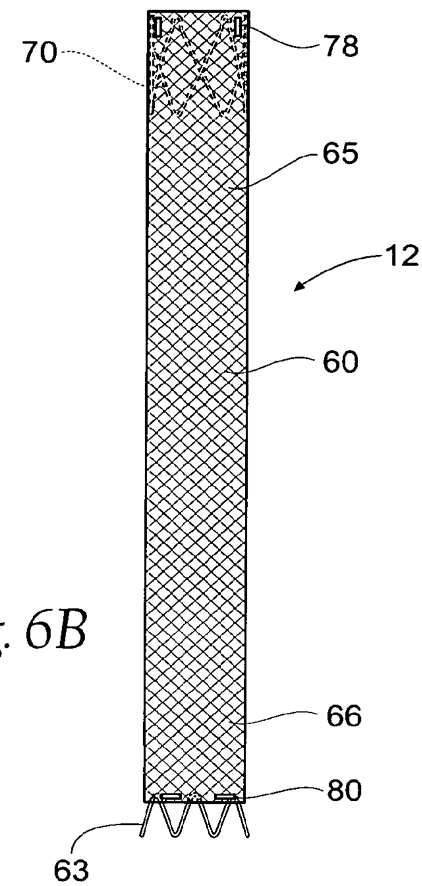


Fig. 6B

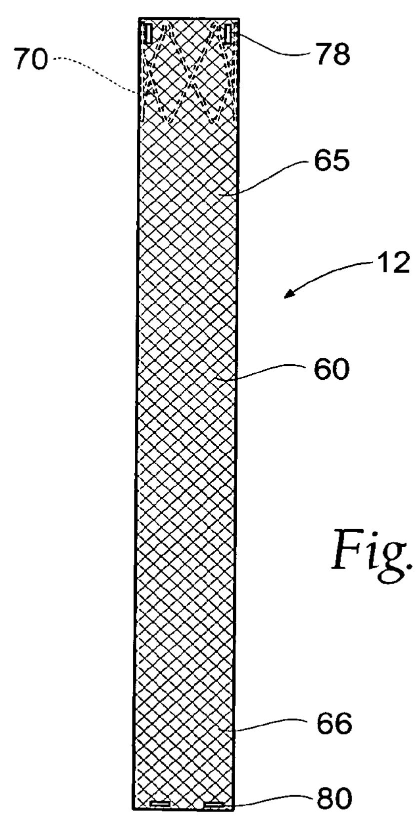


Fig. 6C

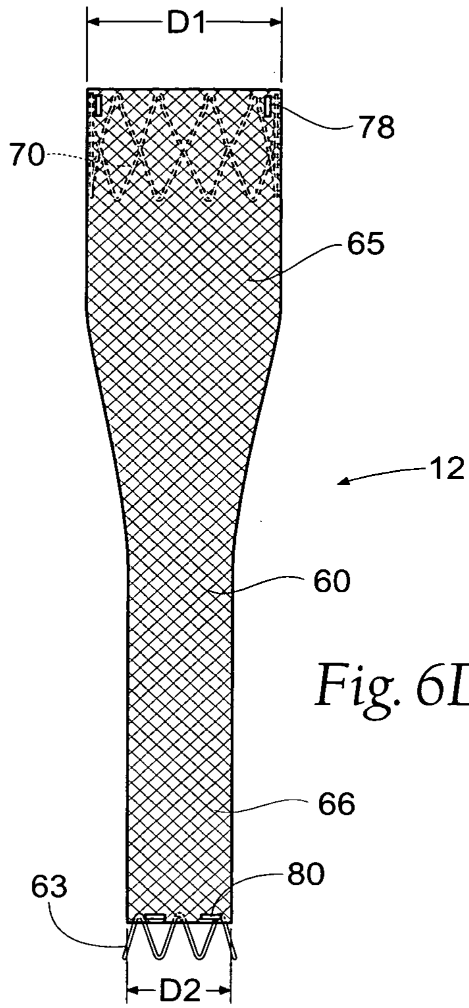


Fig. 6D

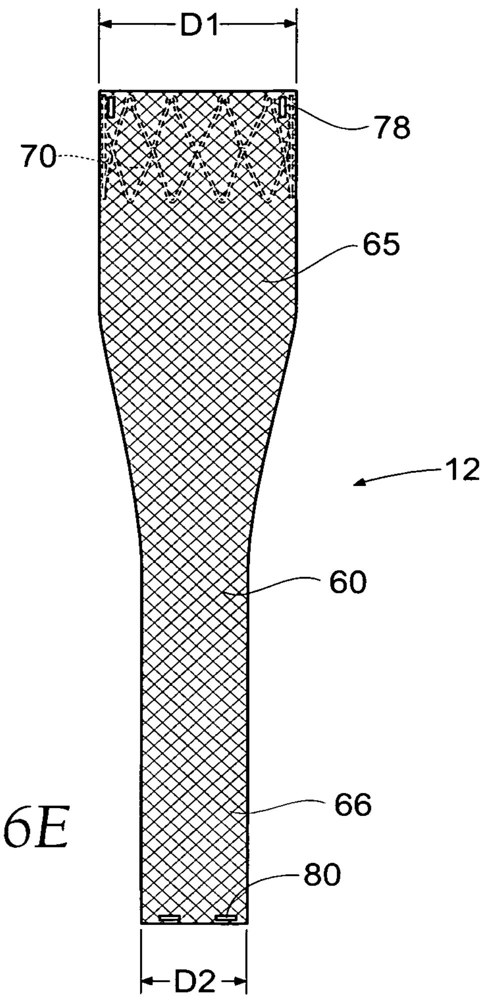


Fig. 6E

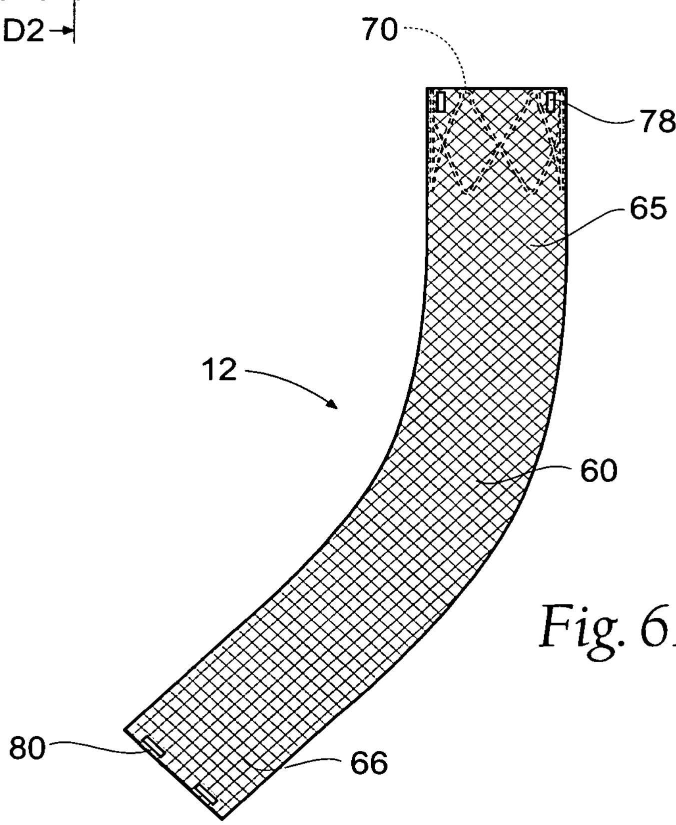


Fig. 6F

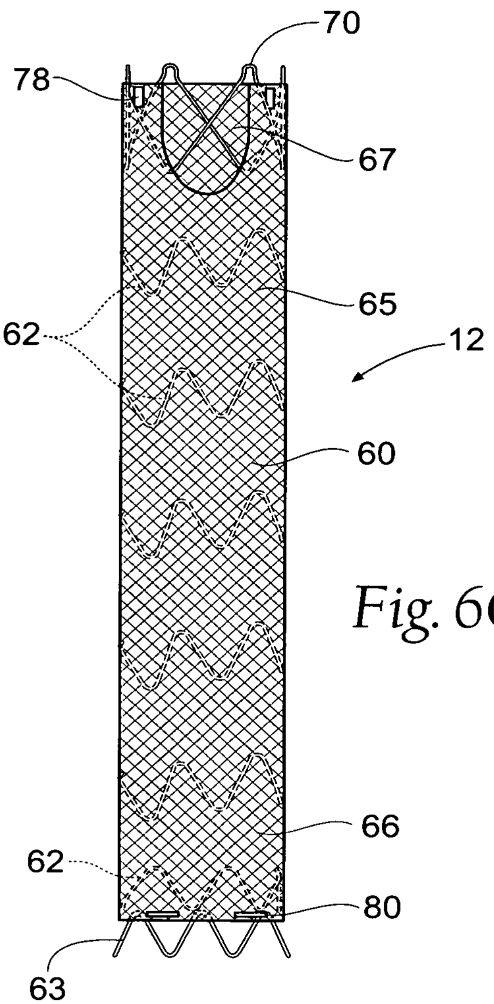


Fig. 6G

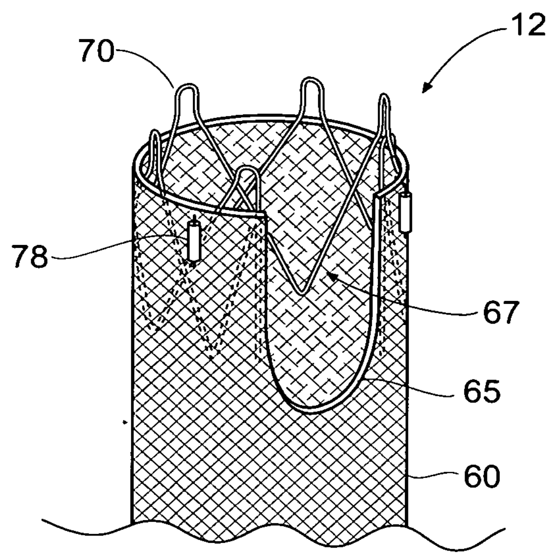


Fig. 6H

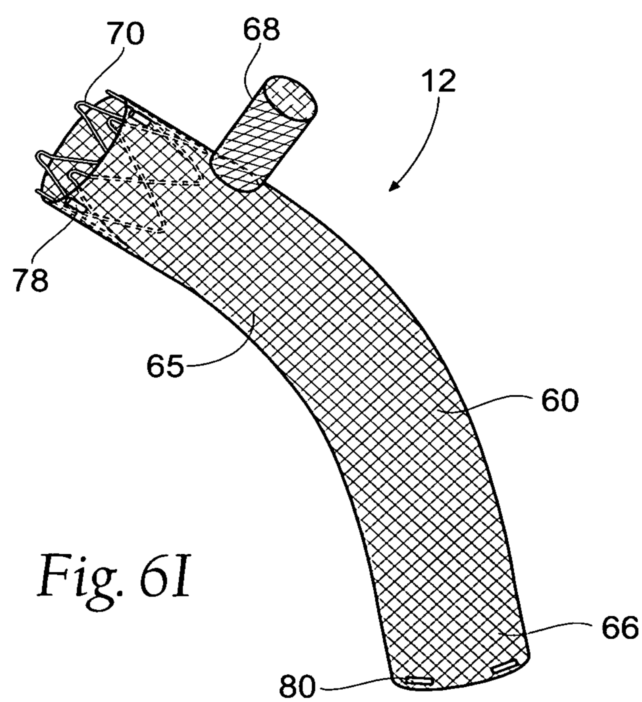


Fig. 6I

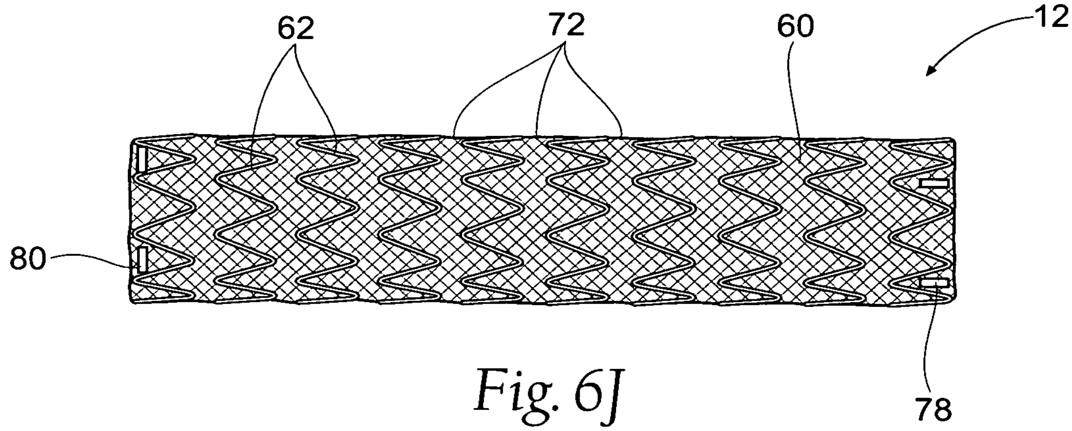
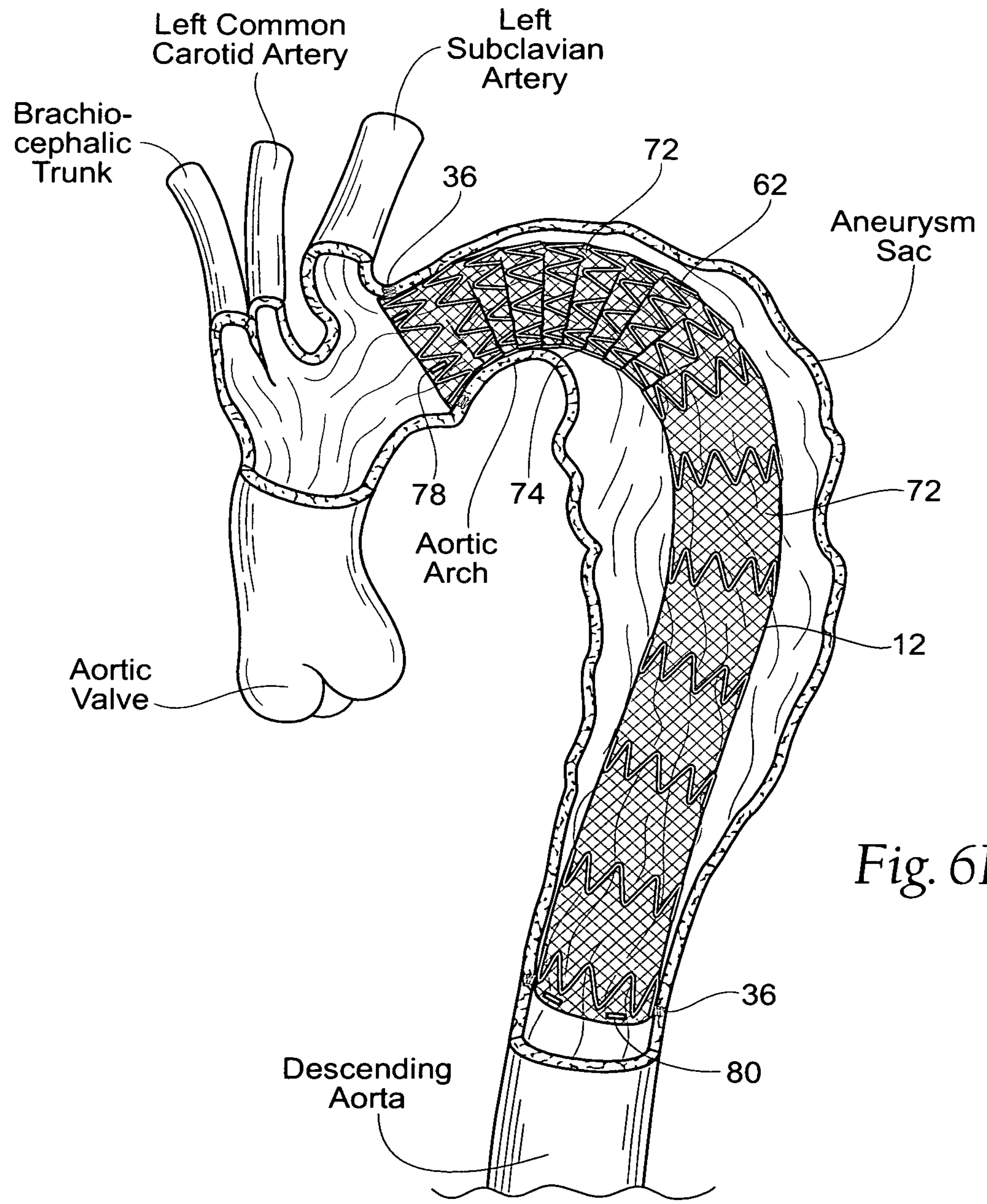

62
72
60
12
80
78

Fig. 6J


Left Common Carotid Artery
Left Subclavian Artery
Brachio-cephalic Trunk
36
72
62
Aneurysm Sac
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74
72
Aortic Arch
12
Aortic Valve
36
80
Descending Aorta

Fig. 6K

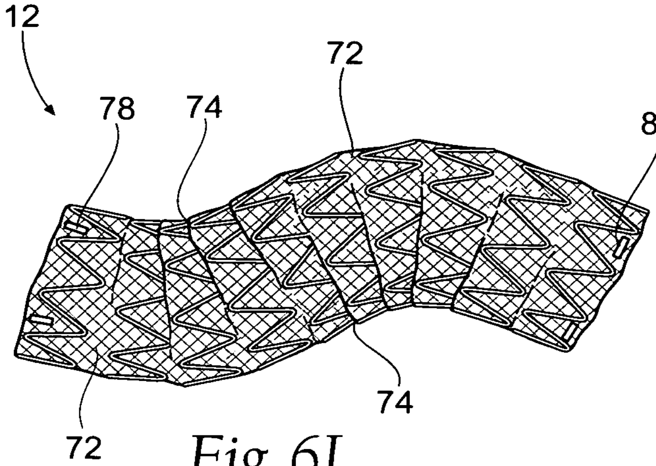


Fig. 6L

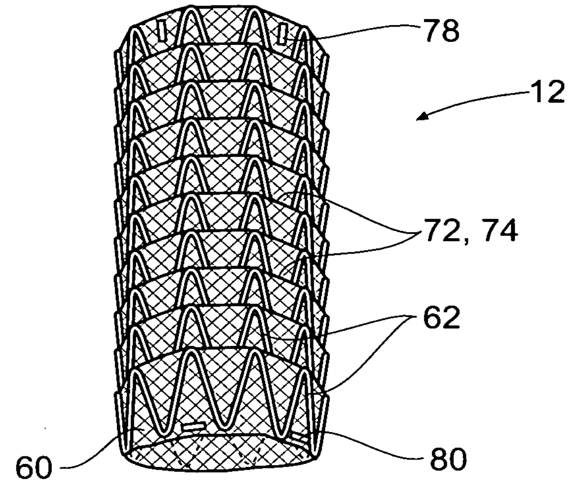


Fig. 6M

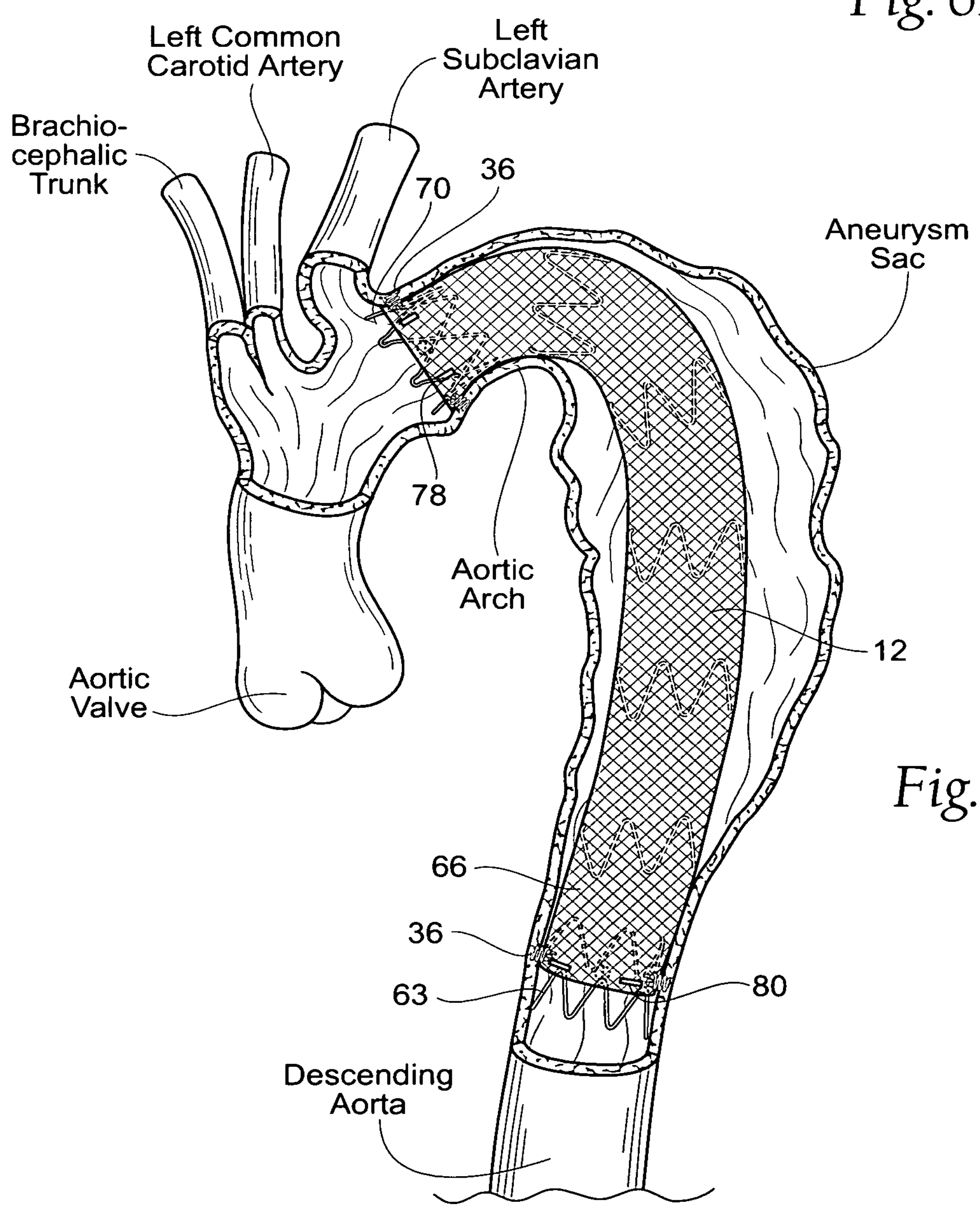


Fig. 7A

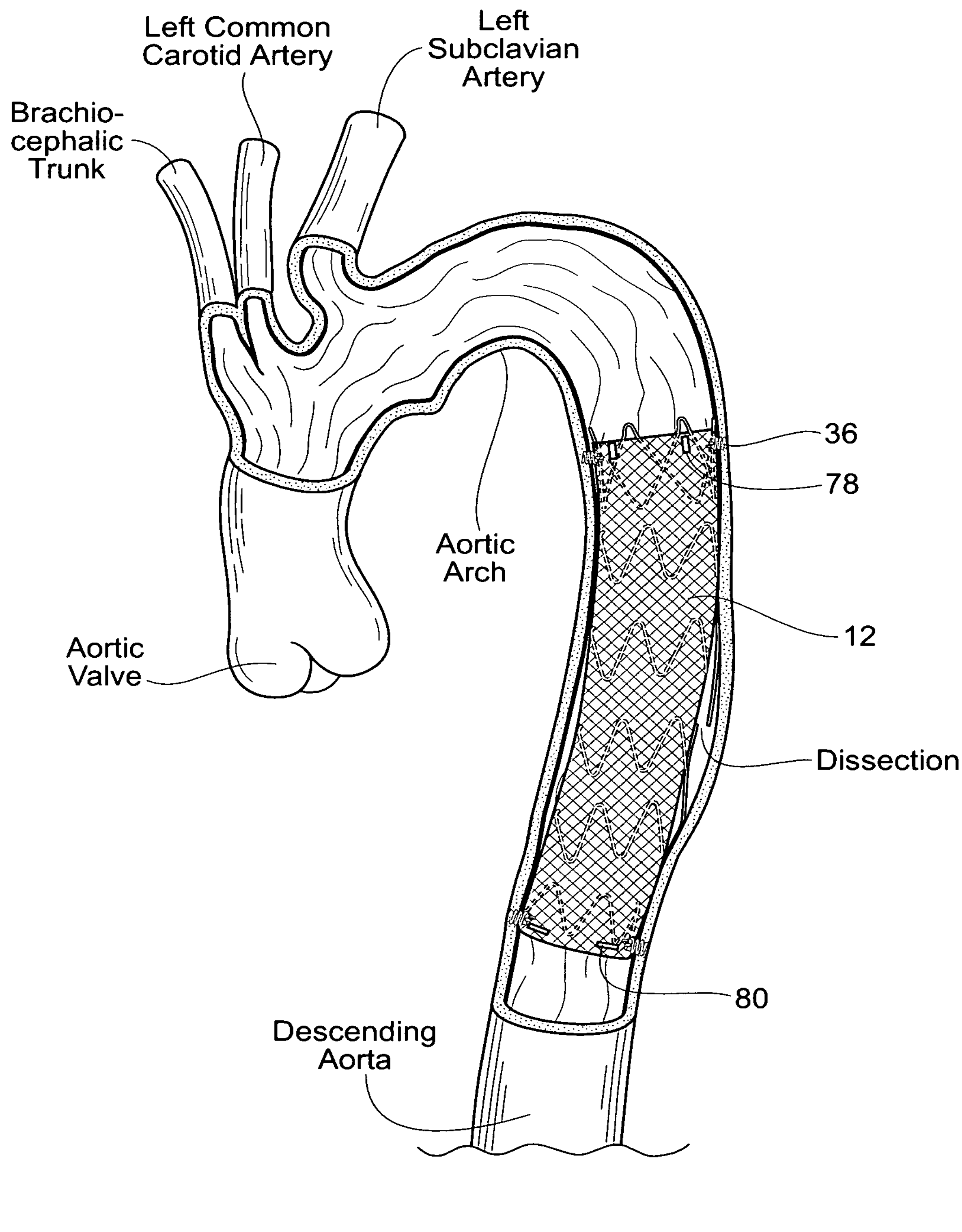

Left Common Carotid Artery
Left Subclavian Artery
Brachio-cephalic Trunk
36
78
Aortic Arch
12
Aortic Valve
Dissection
80
Descending Aorta

Fig. 7B

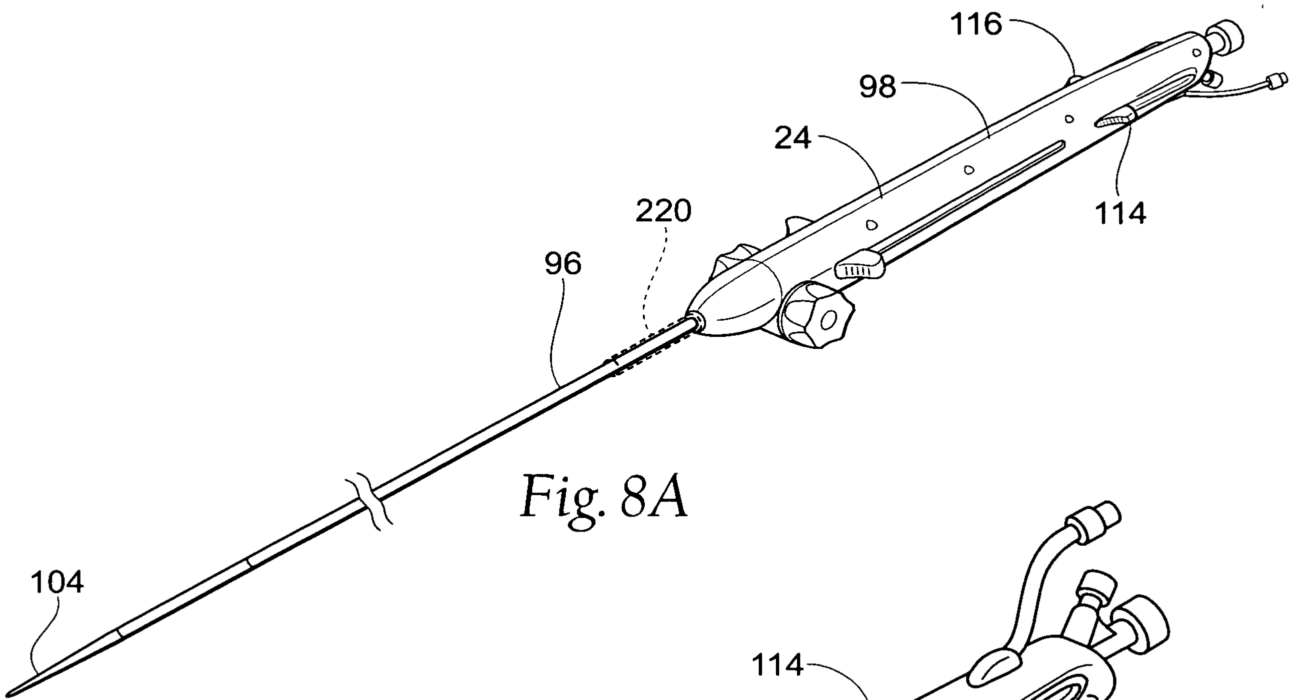


Fig. 8A

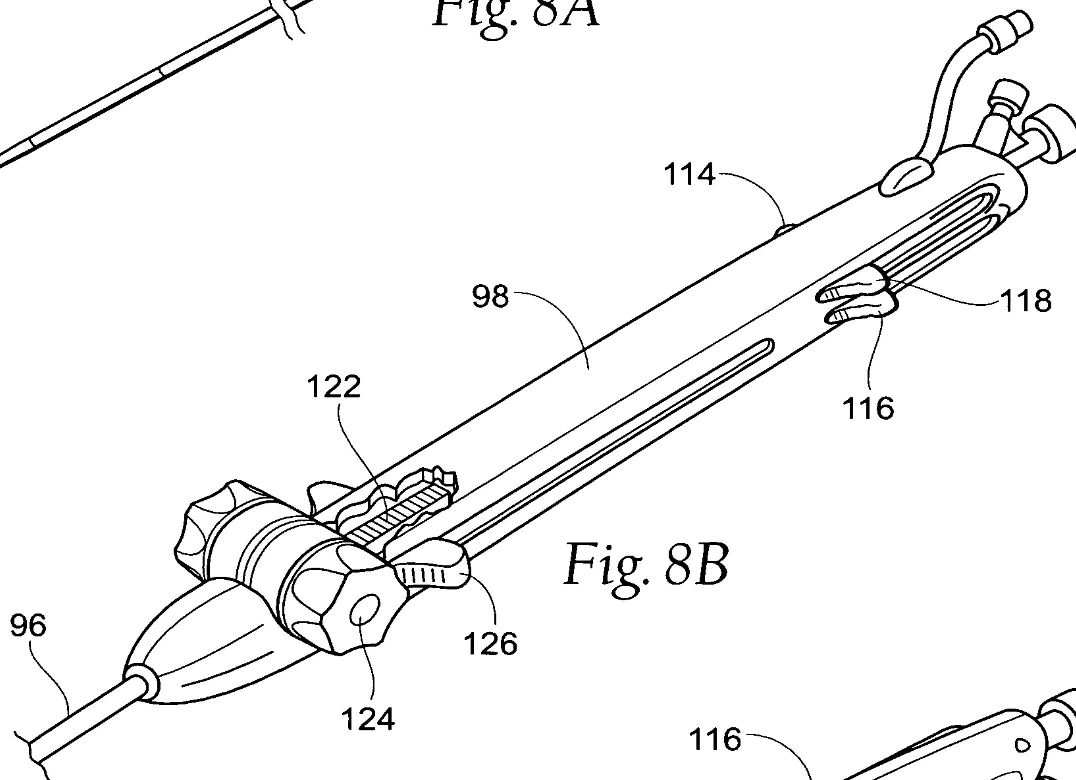


Fig. 8B

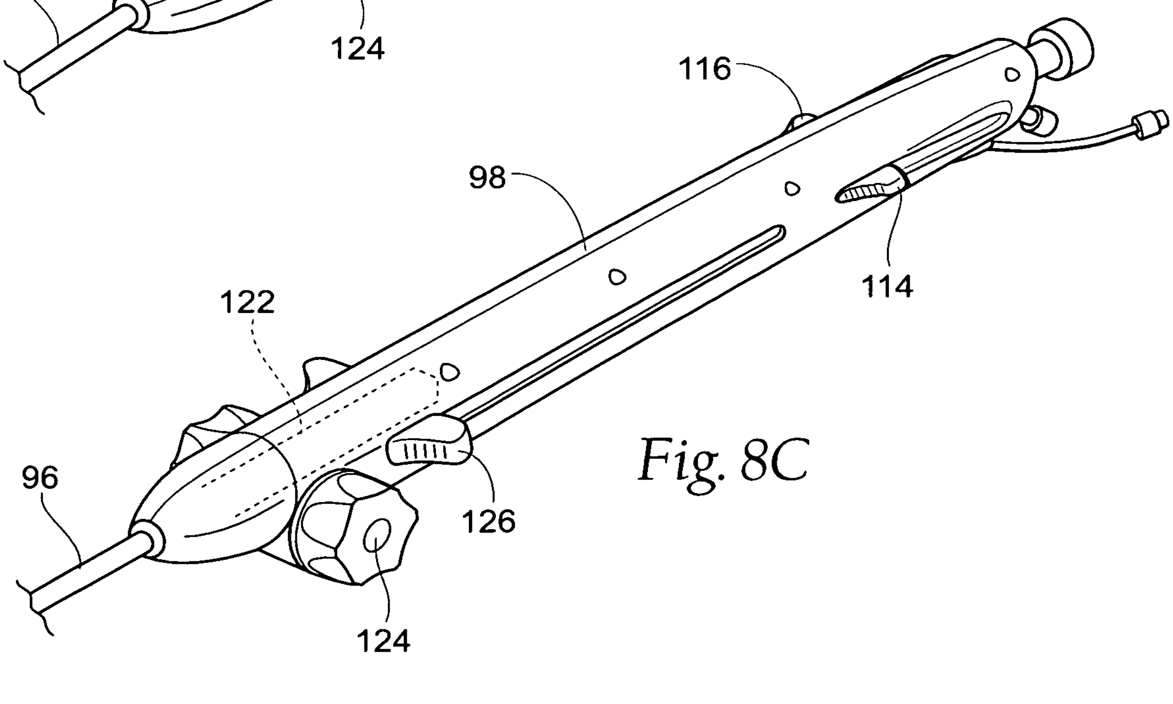
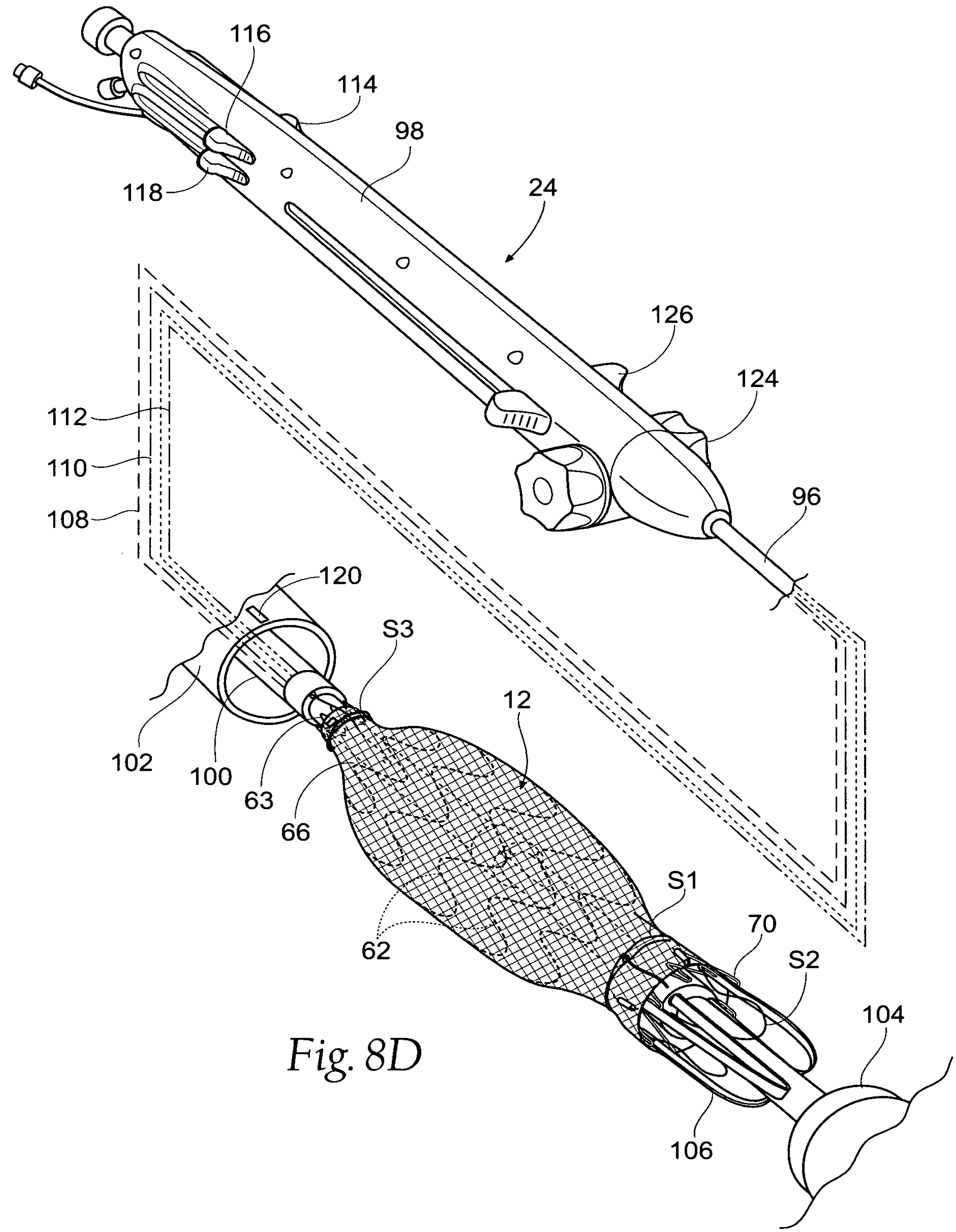


Fig. 8C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S3
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S1
70
S2
62
104
106

Fig. 8D

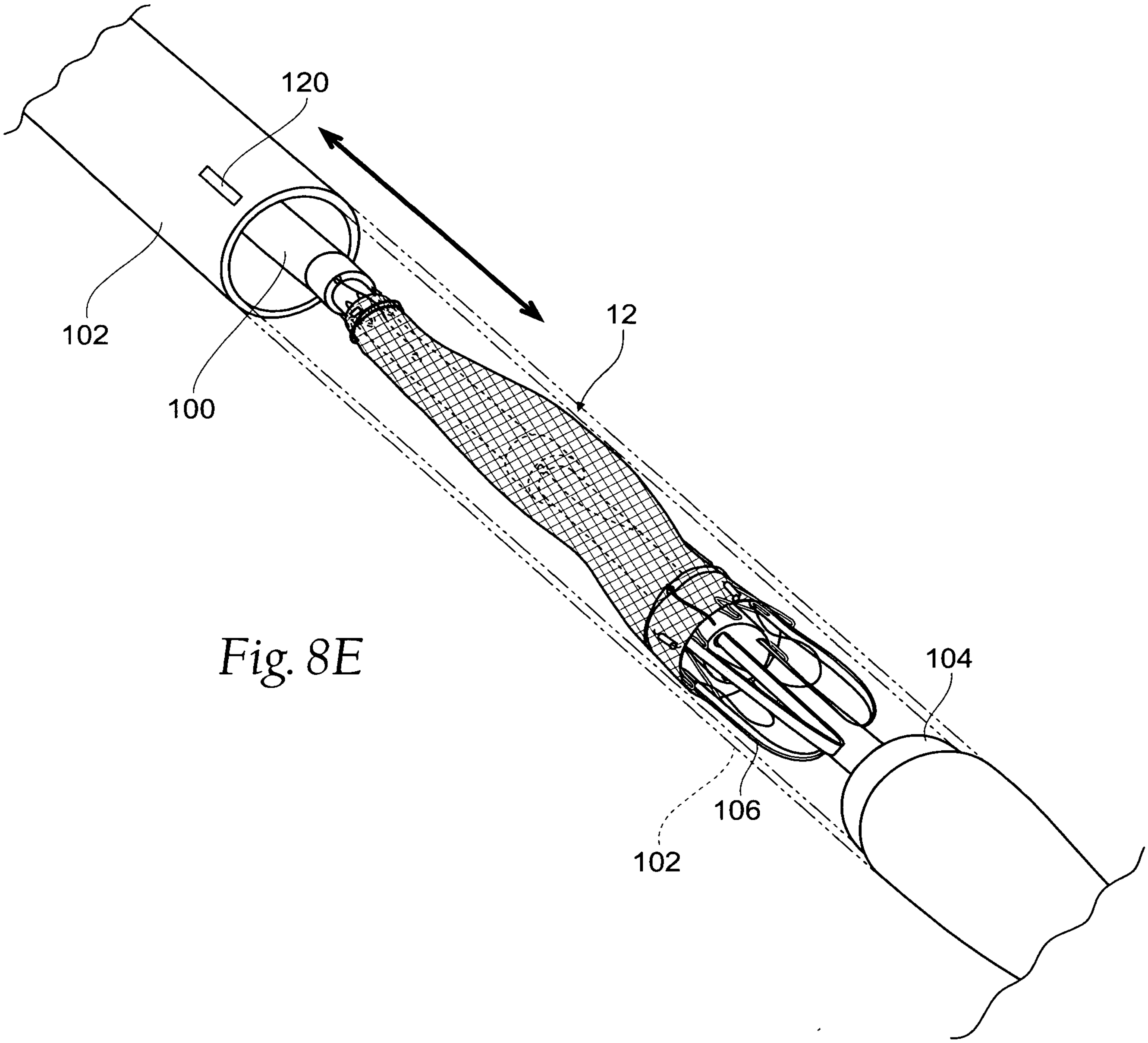


Fig. 8E

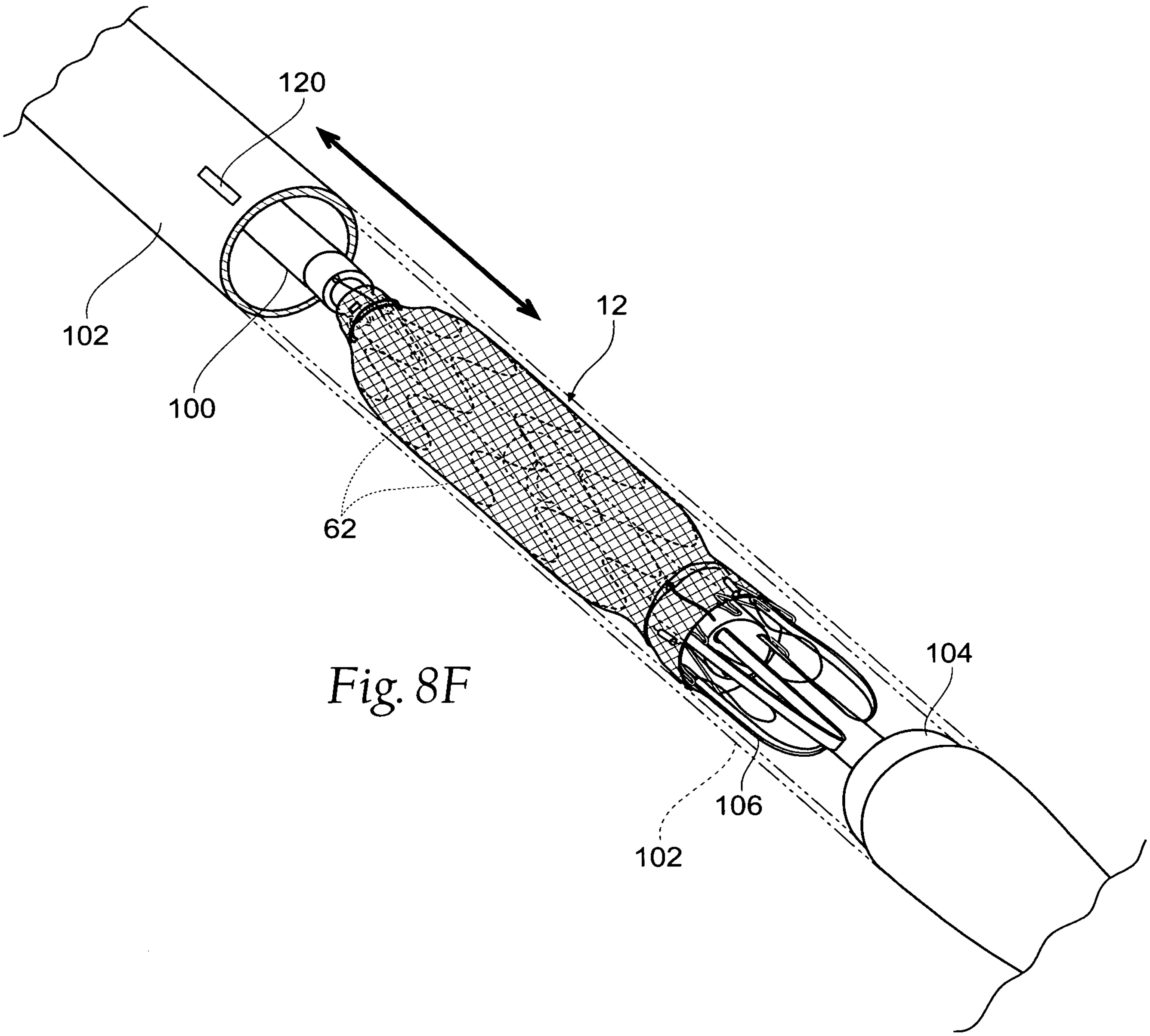


Fig. 8F

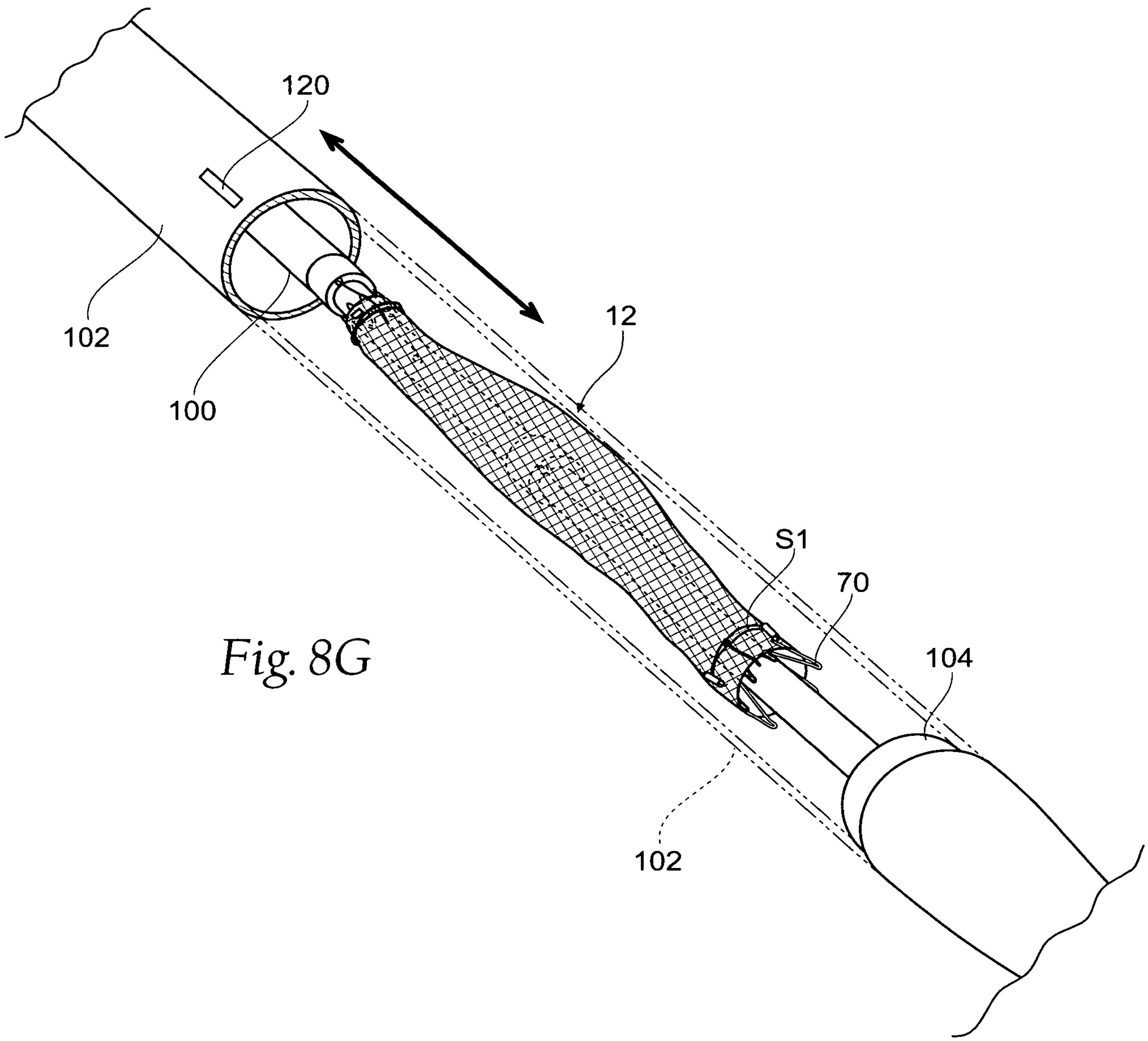


Fig. 8G

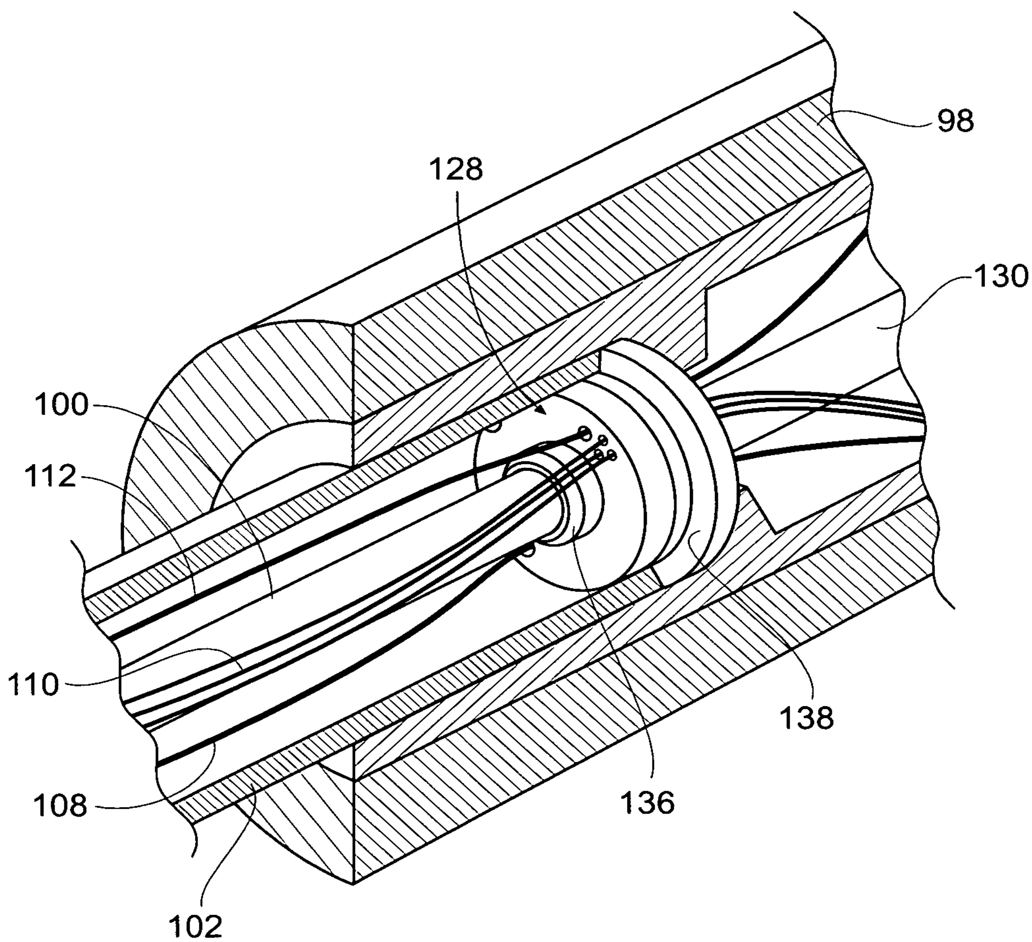
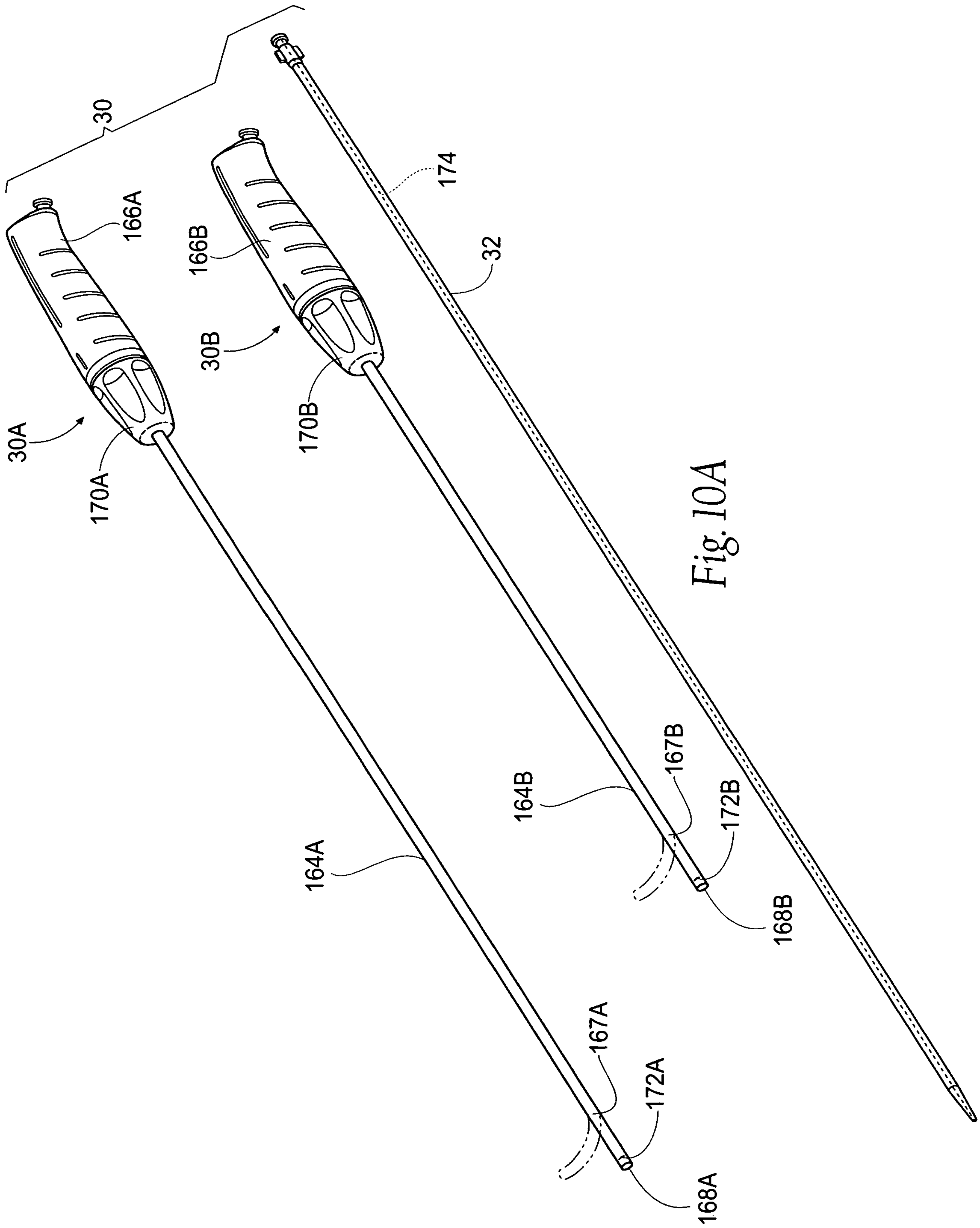


Fig. 9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164B
172B
164A
168B
167A
172A
168A

Fig. 10A

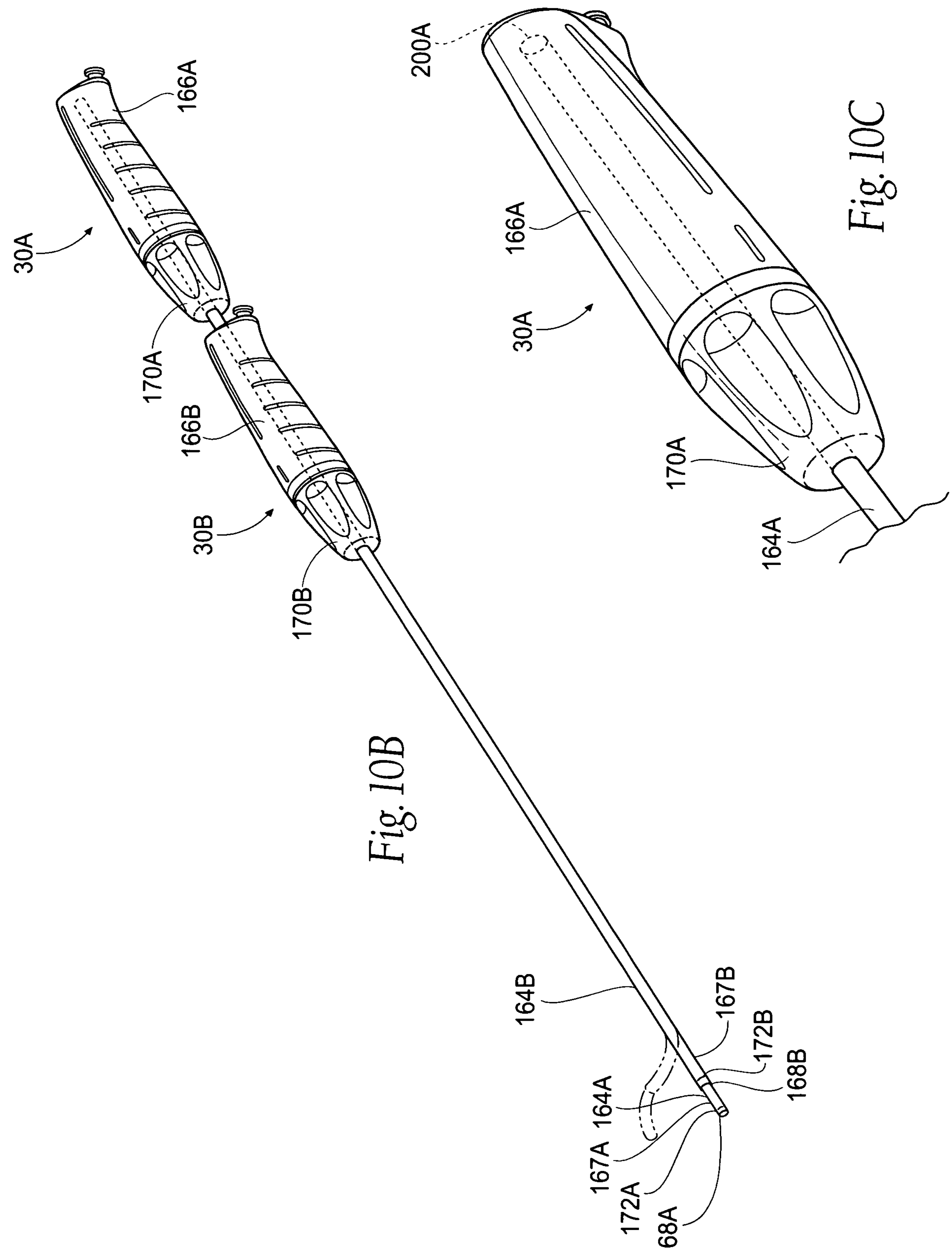


Fig. 10B

Fig. 10C

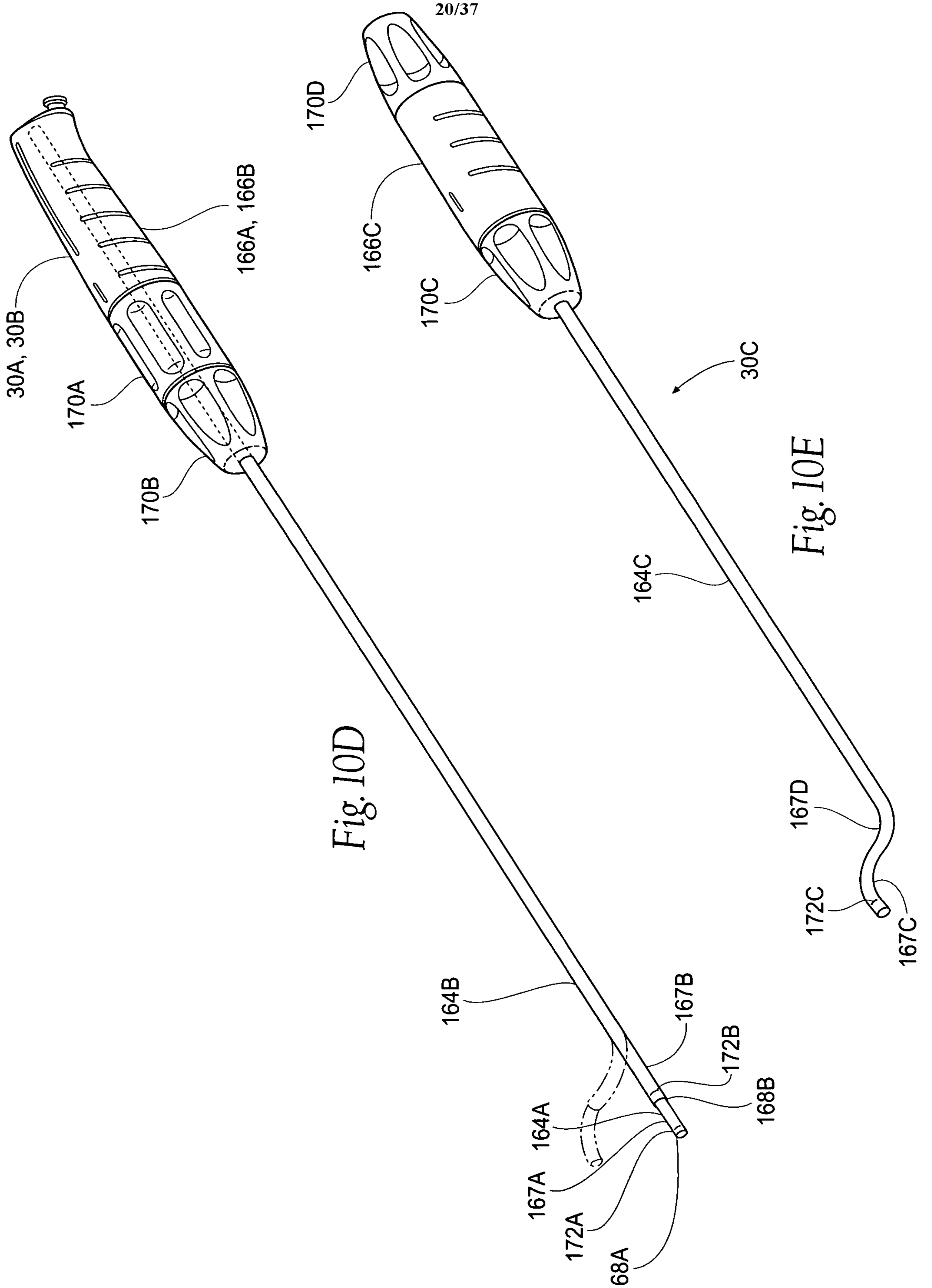


Fig. 10D

Fig. 10E

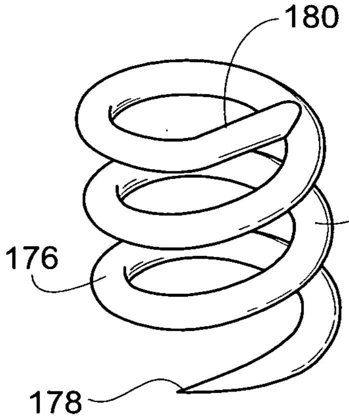


Fig. 11A

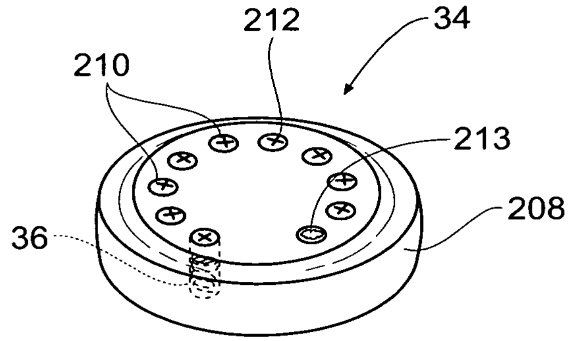


Fig. 11B

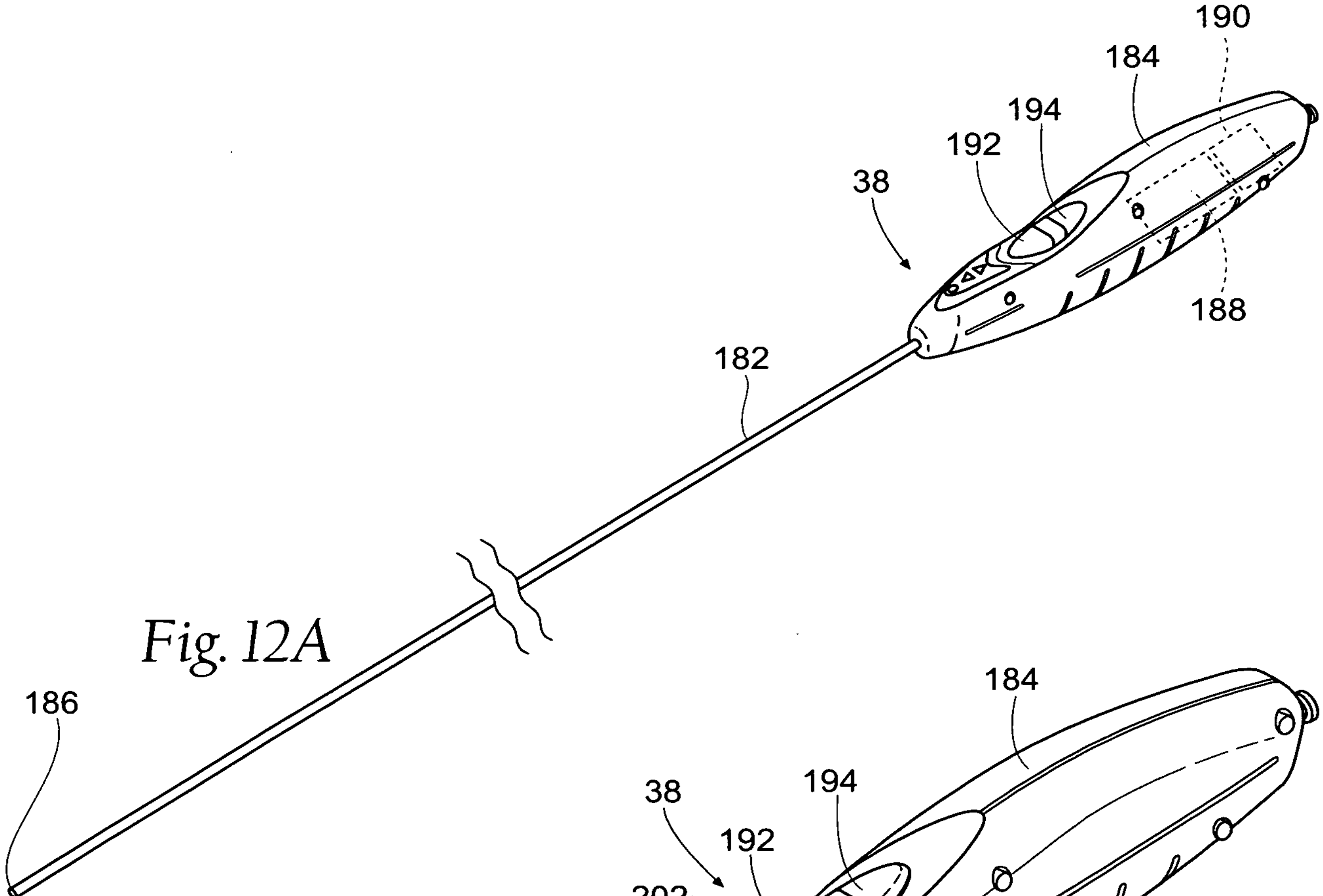


Fig. 12A

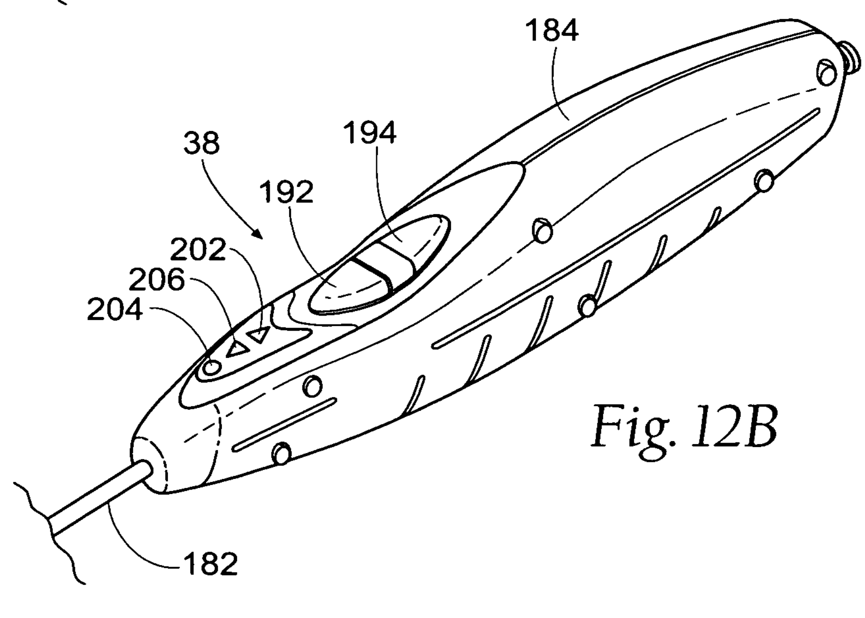


Fig. 12B

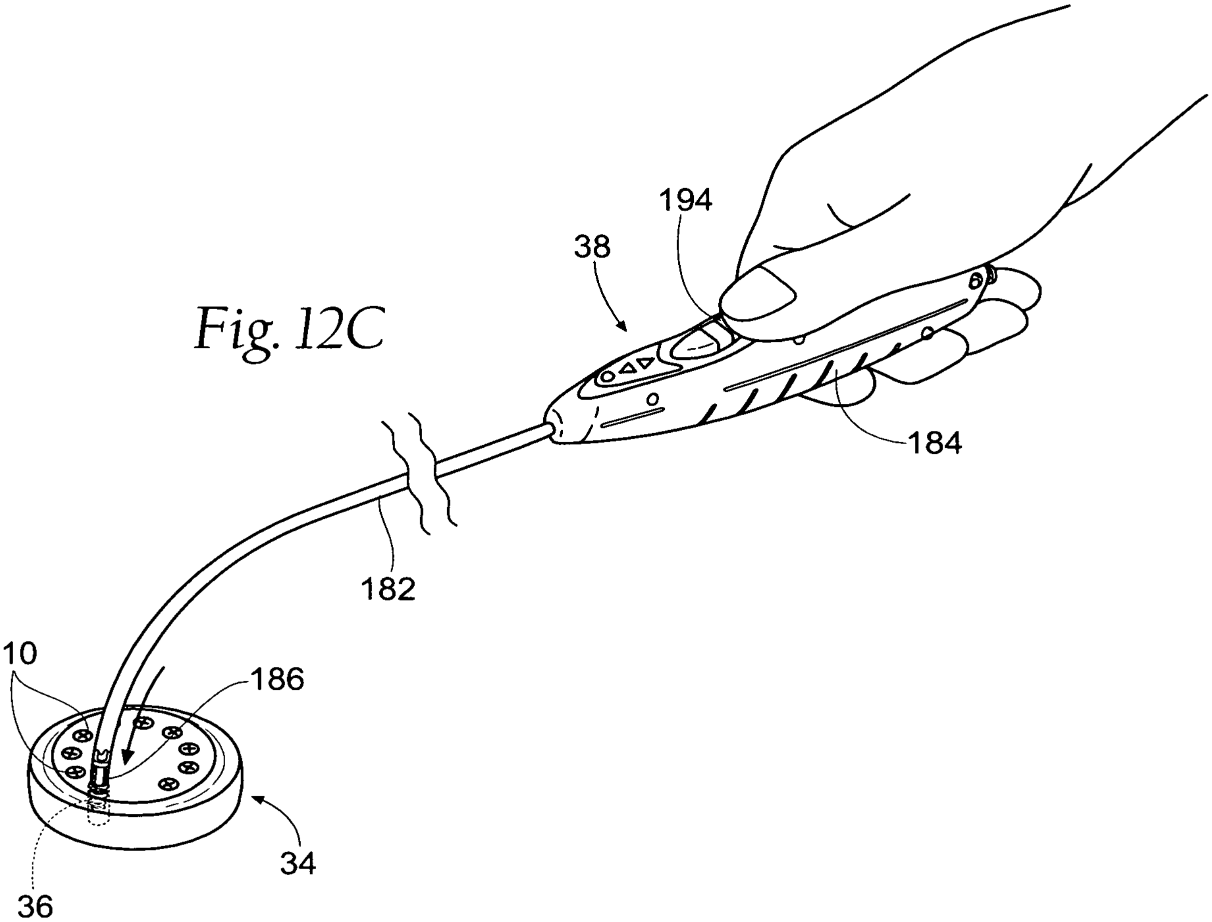


Fig. 12C

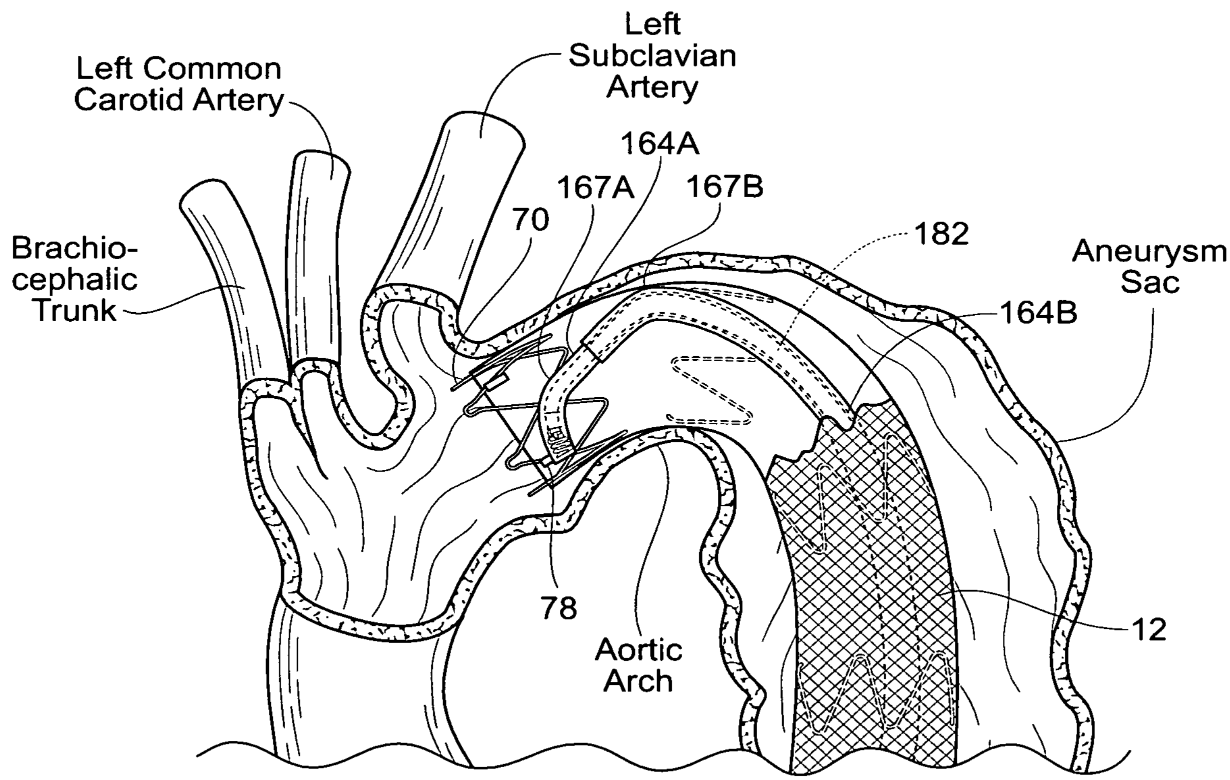


Fig. 13A

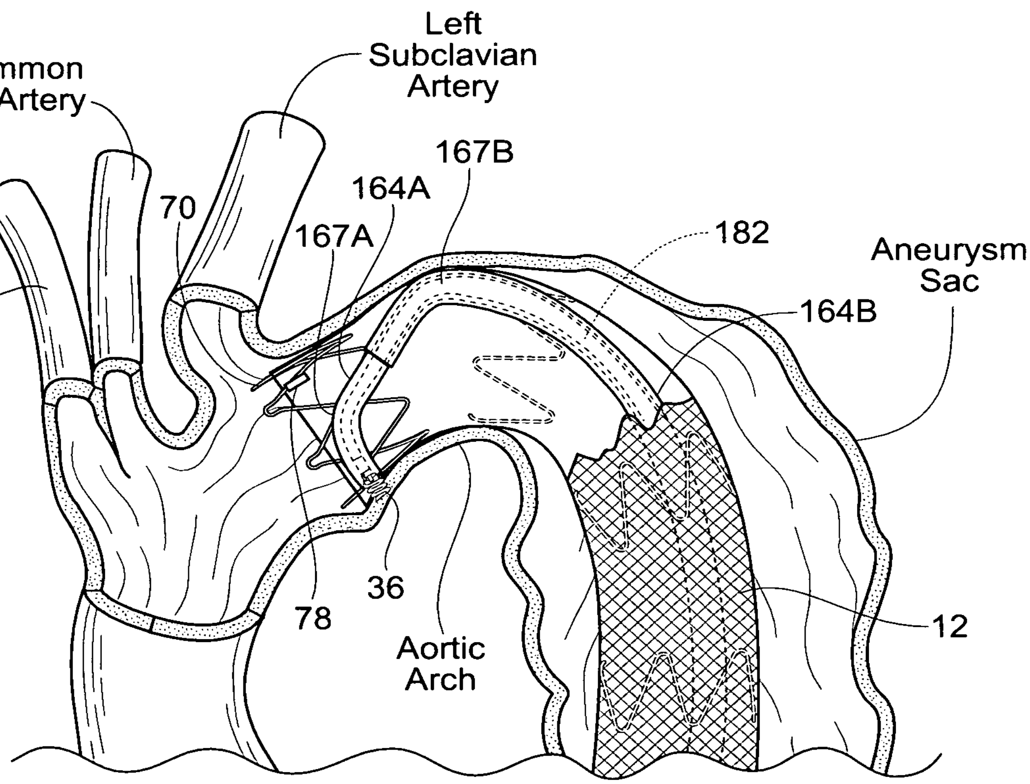

Left Common Carotid Artery
Left Subclavian Artery
Brachio-cephalic Trunk
70
164A
167B
167A
182
Aneurysm Sac
164B
36
78
Aortic Arch
12

Fig. 13B

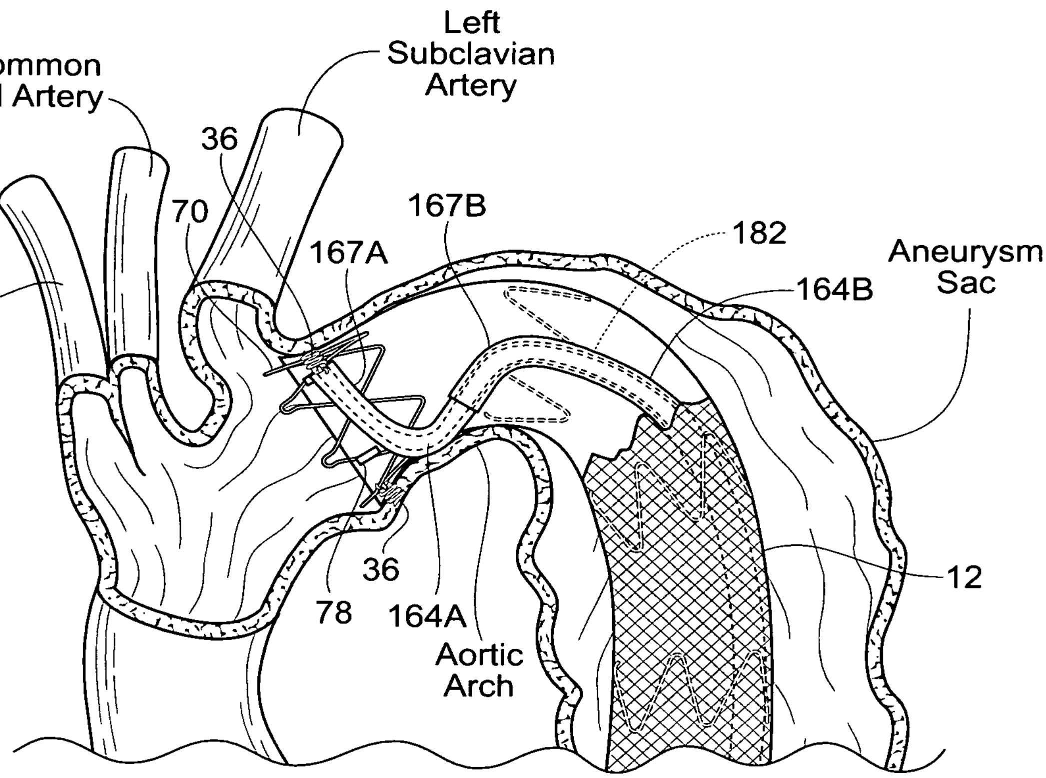


Fig. 13C

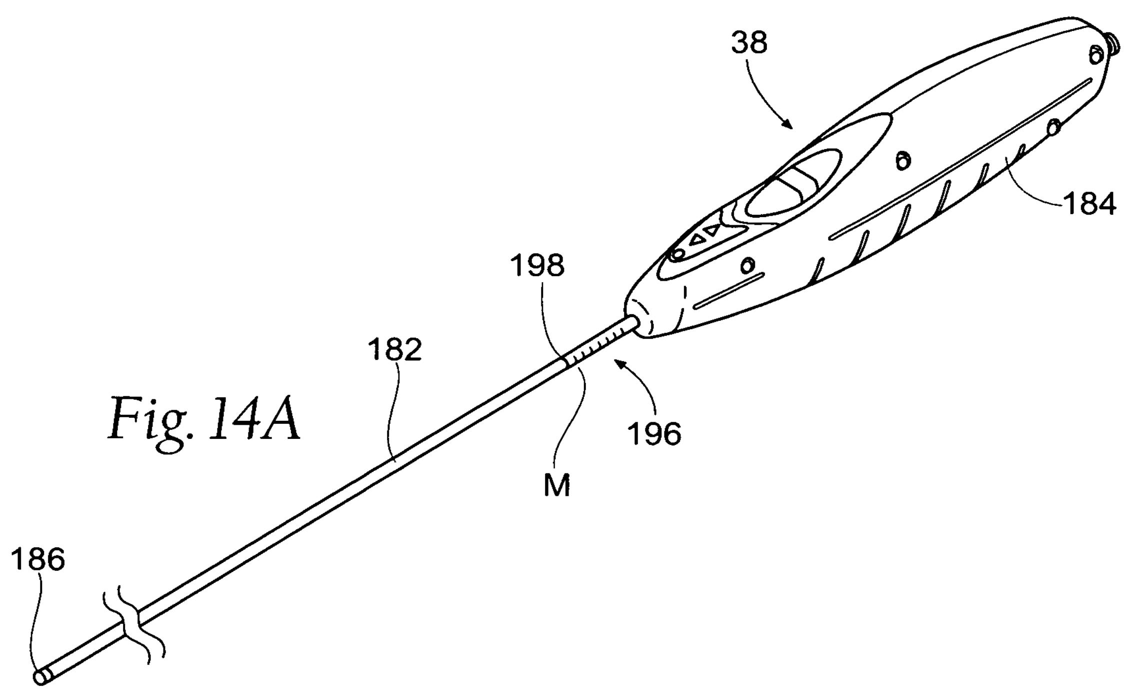


Fig. 14A

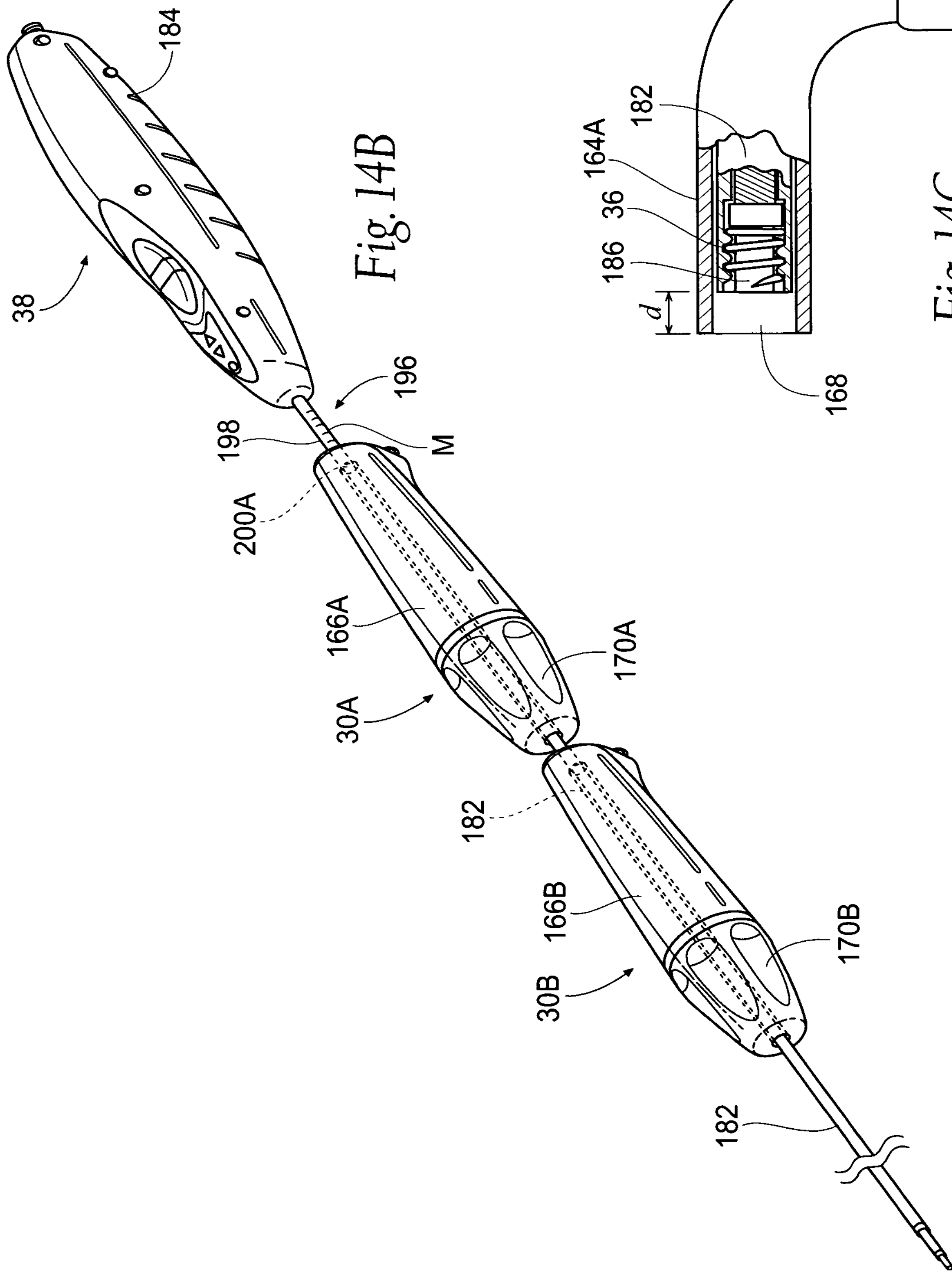


Fig. 14B

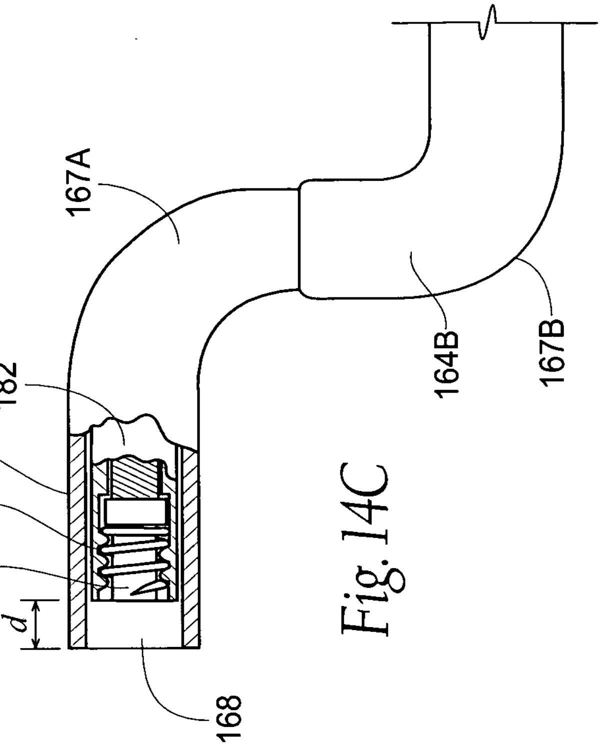
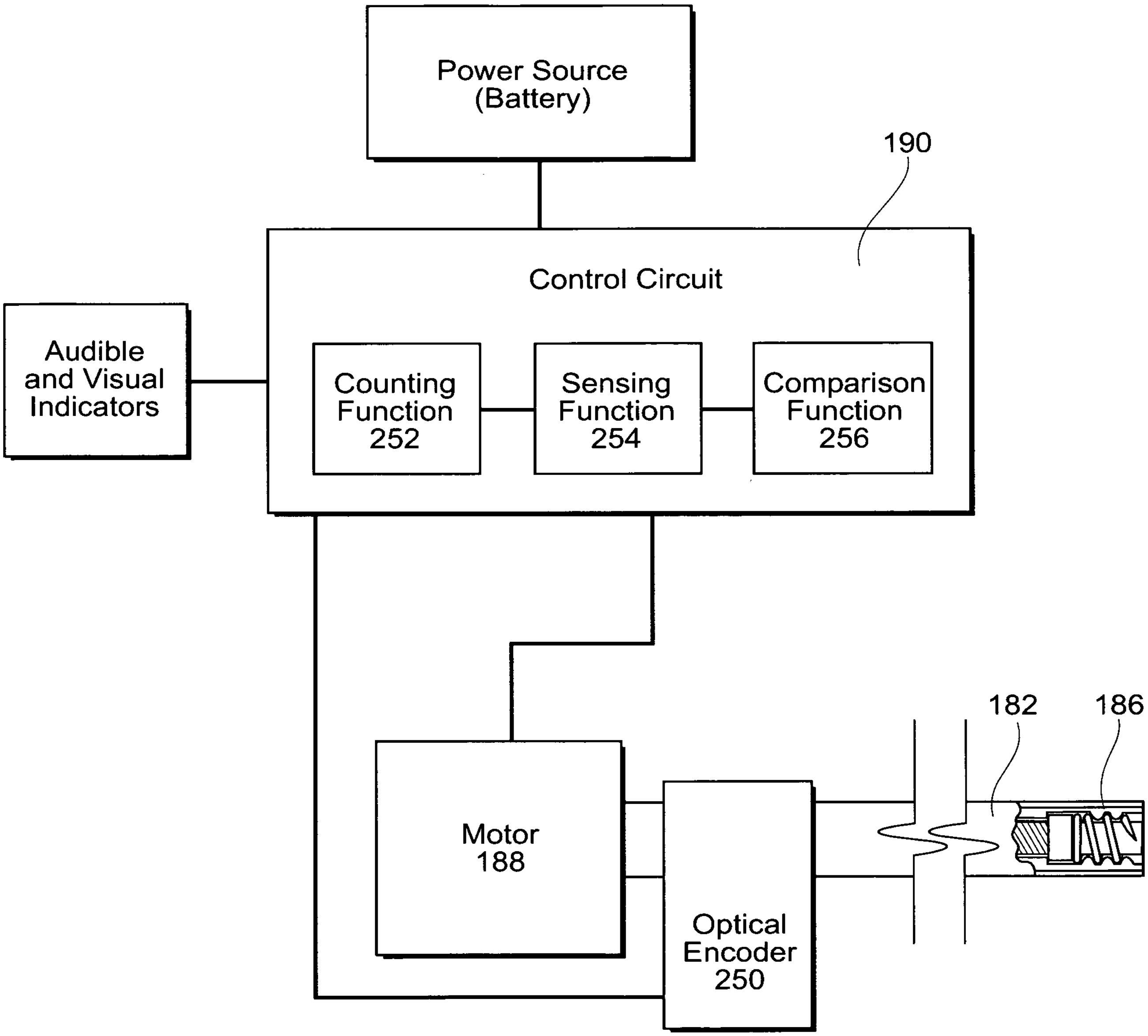


Fig. 14C


Power Source
(Battery)
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Control Circuit
Audible
and Visual
Indicators
Counting
Function
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Sensing
Function
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Comparison
Function
256
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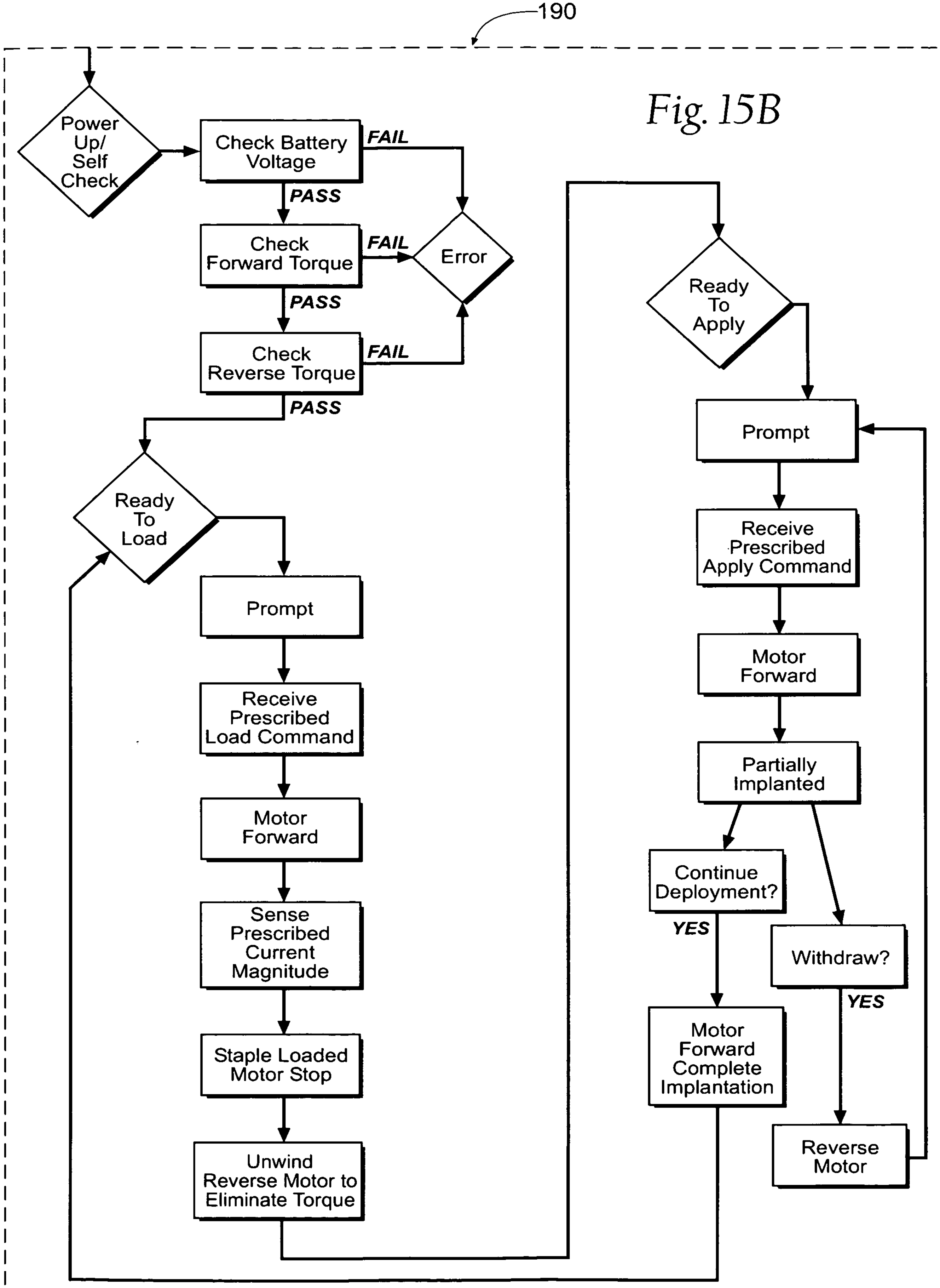
186
Motor
188
Optical
Encoder
250

Fig. 15A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Power Up/ Self Check
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FAIL
PASS
Check Forward Torque
FAIL
Error
PASS
Check Reverse Torque
FAIL
PASS
Ready To Load
Prompt
Receive Prescribed Load Command
Motor Forward
Sense Prescribed Current Magnitude
Staple Loaded Motor Stop
Unwind Reverse Motor to Eliminate Torque
Ready To Apply
Prompt
Receive Prescribed Apply Command
Motor Forward
Partially Implanted
Continue Deployment?
YES
Motor Forward Complete Implantation
Withdraw?
YES
Reverse Motor

Fig. 15B

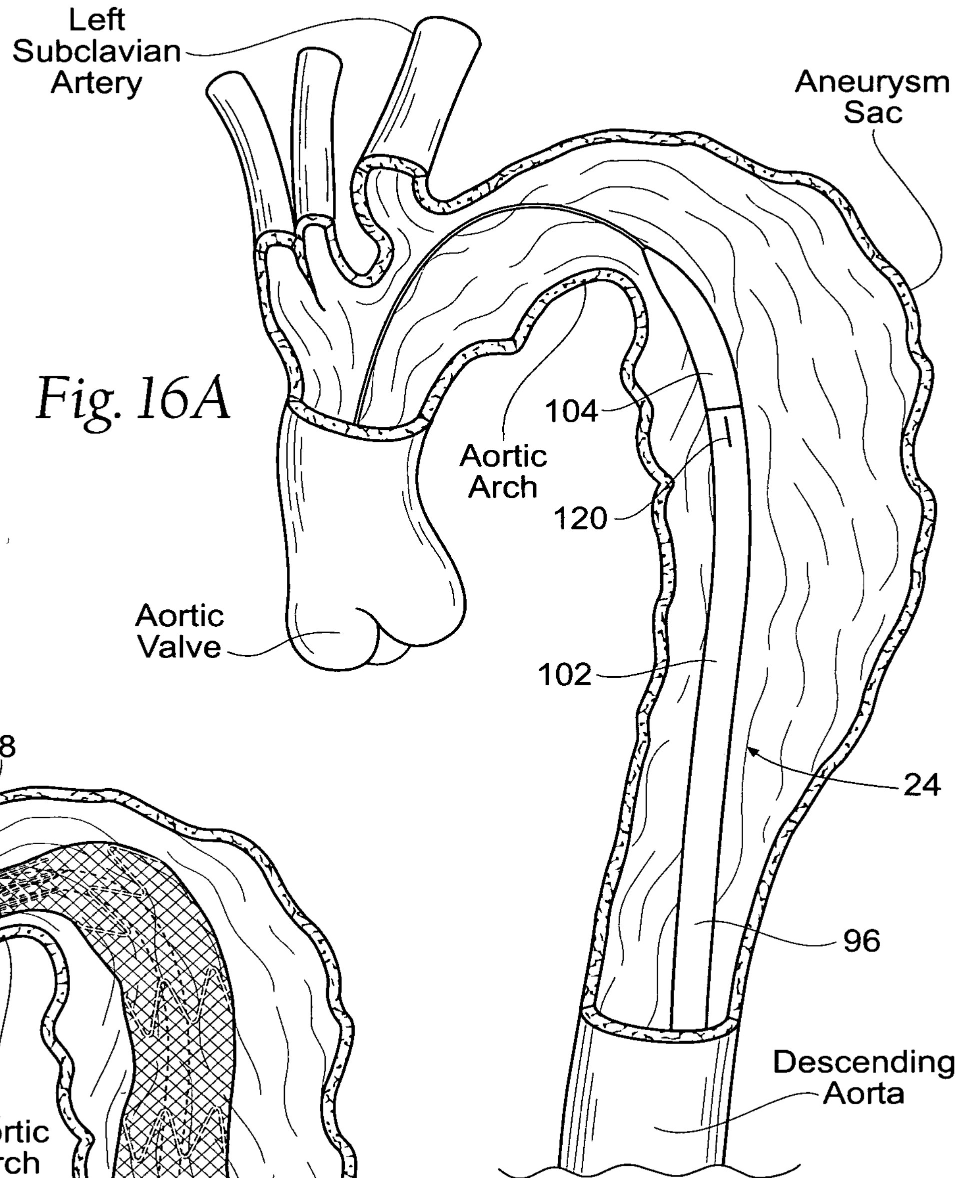


Fig. 16A

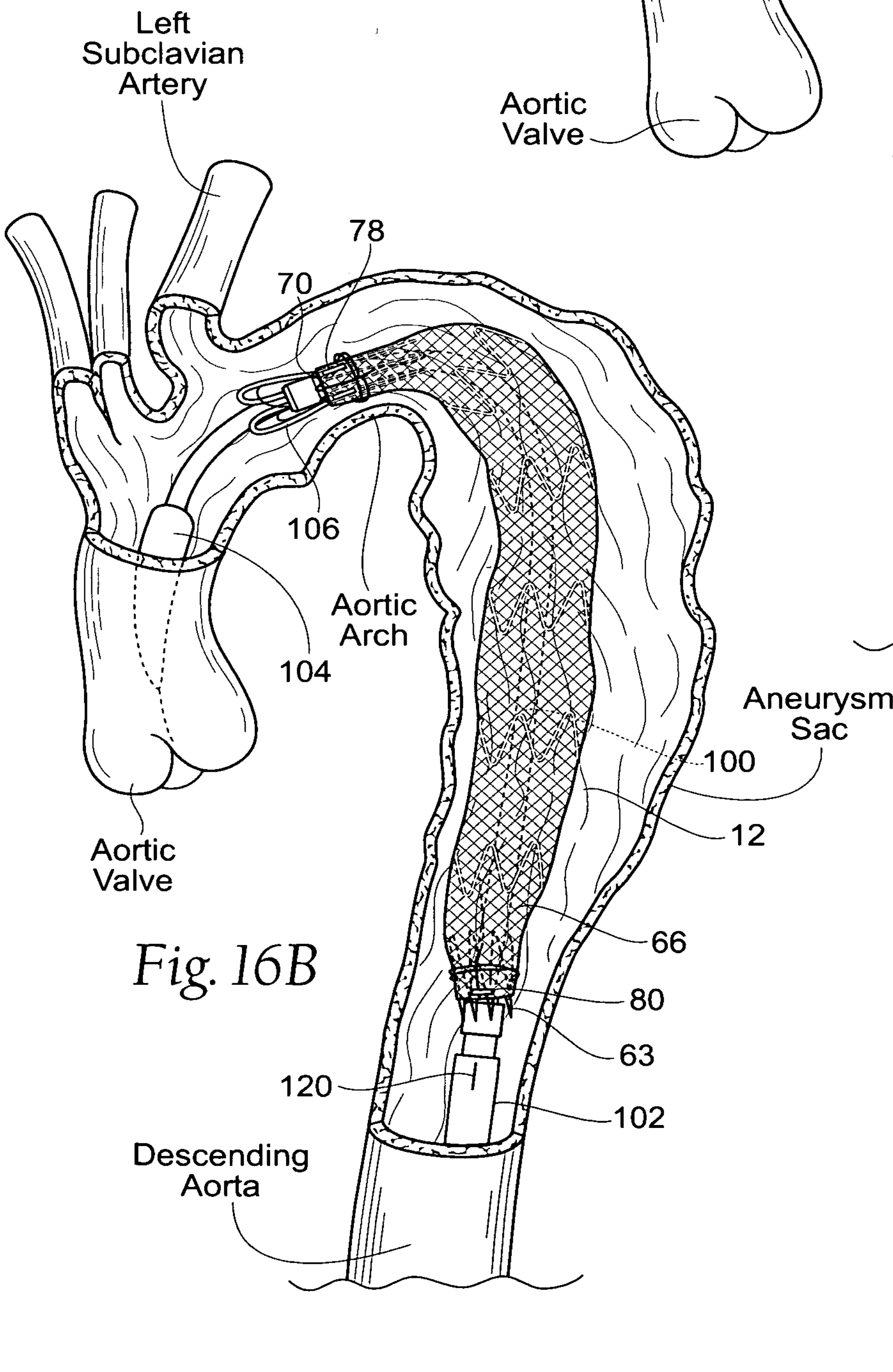


Fig. 16B

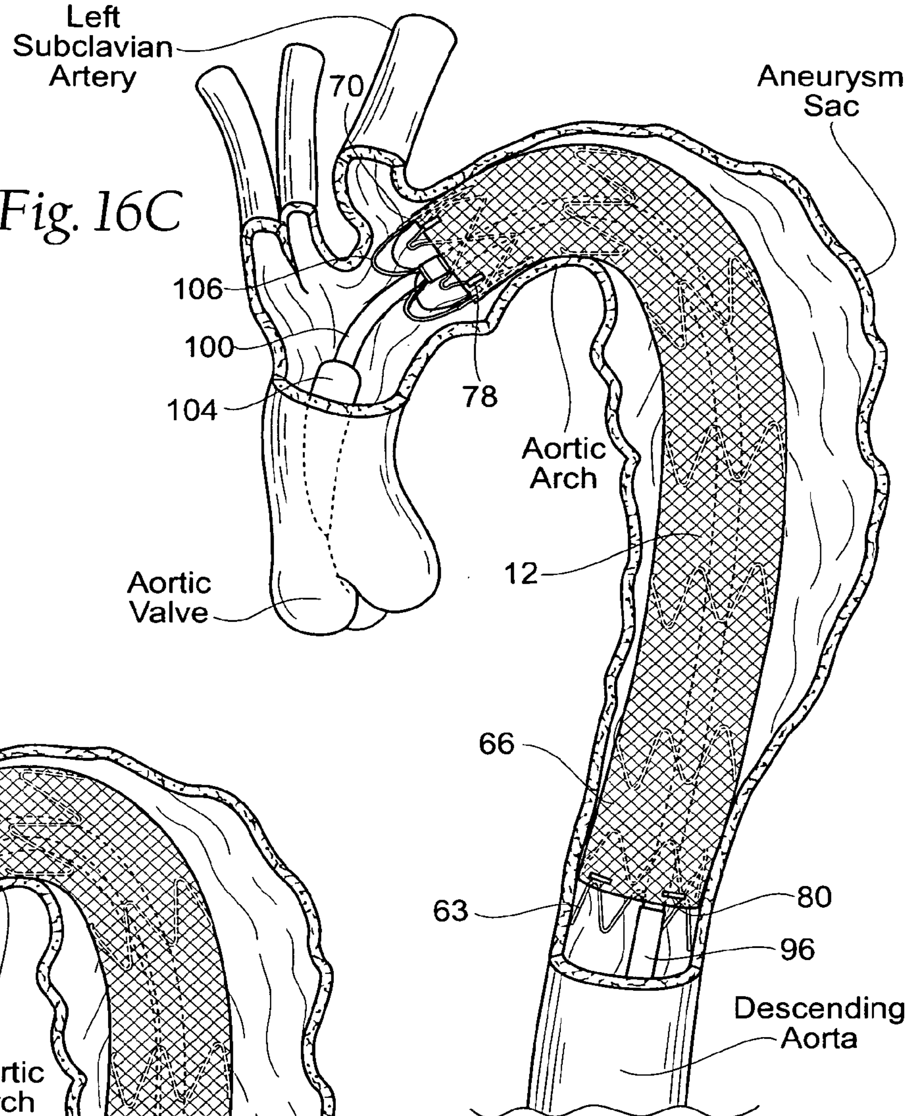


Fig. 16C

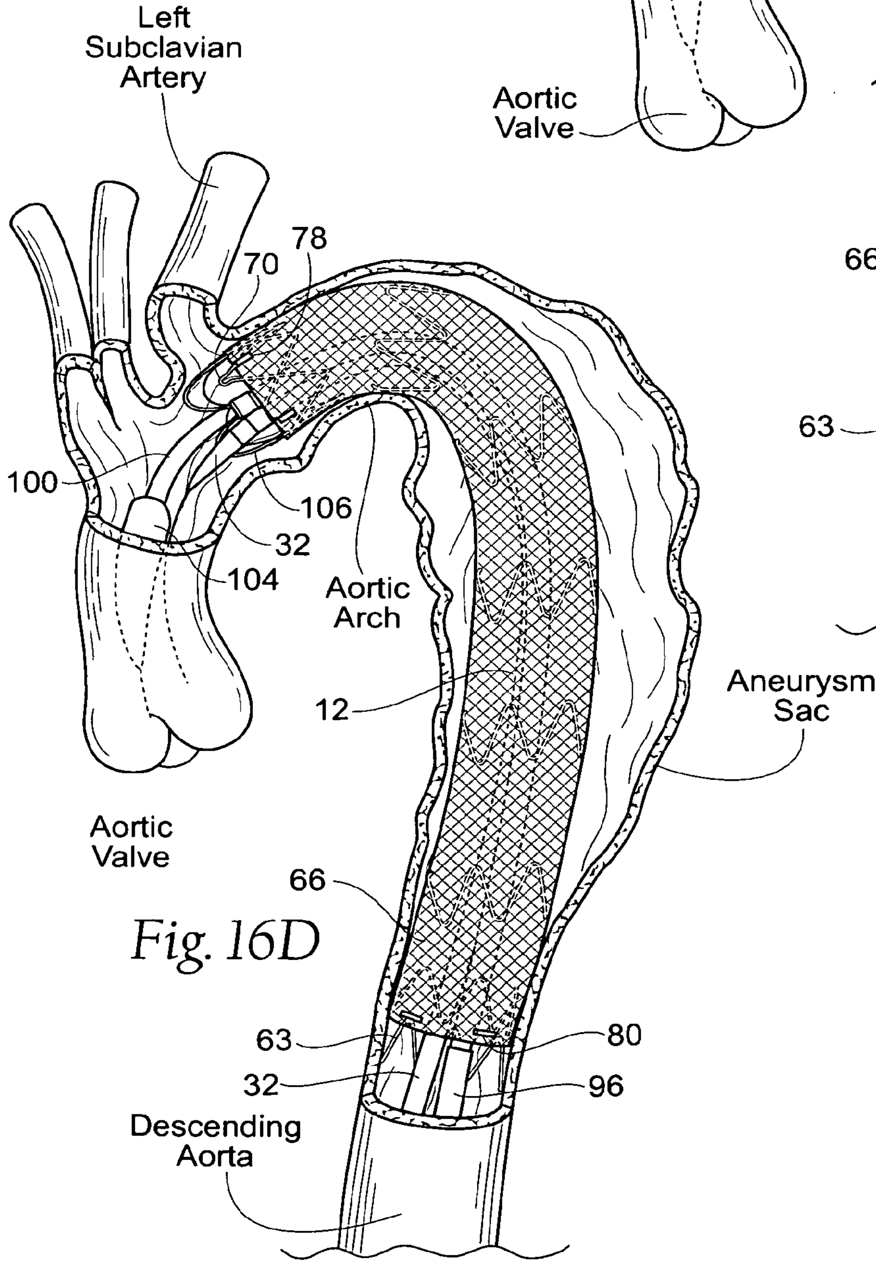


Fig. 16D

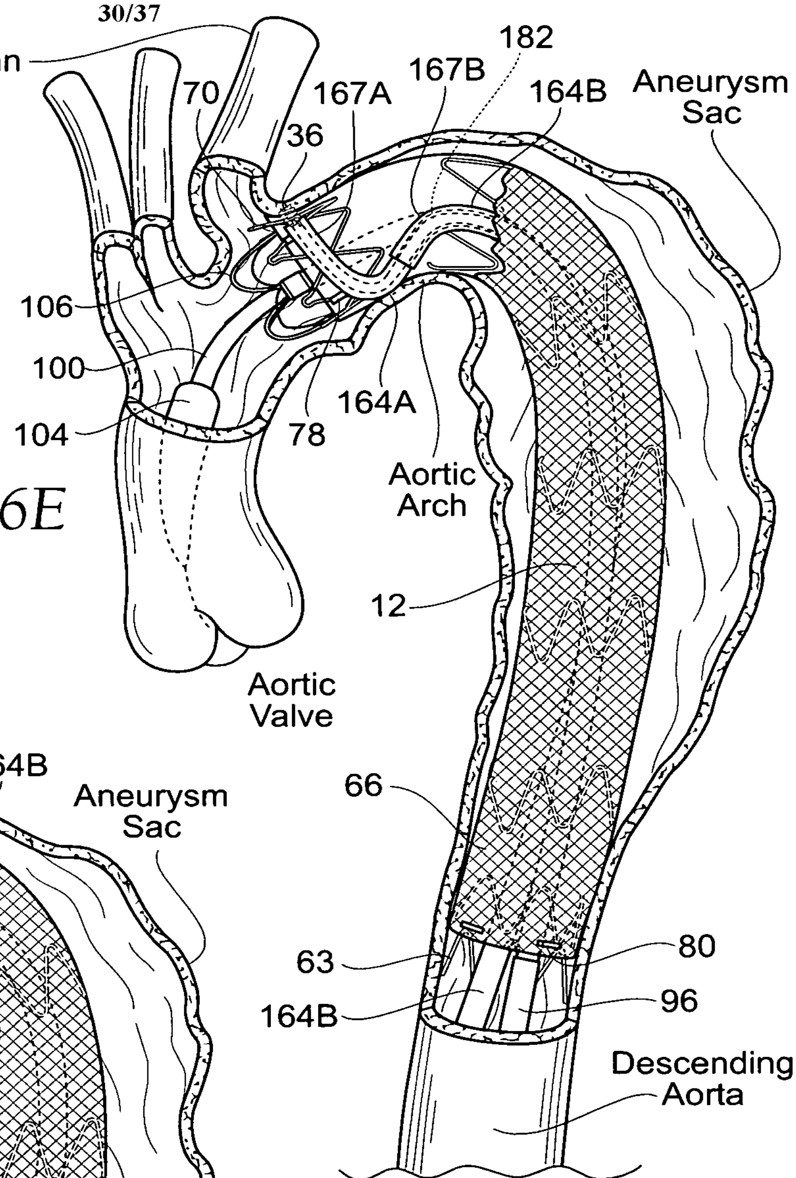


Fig. 16E

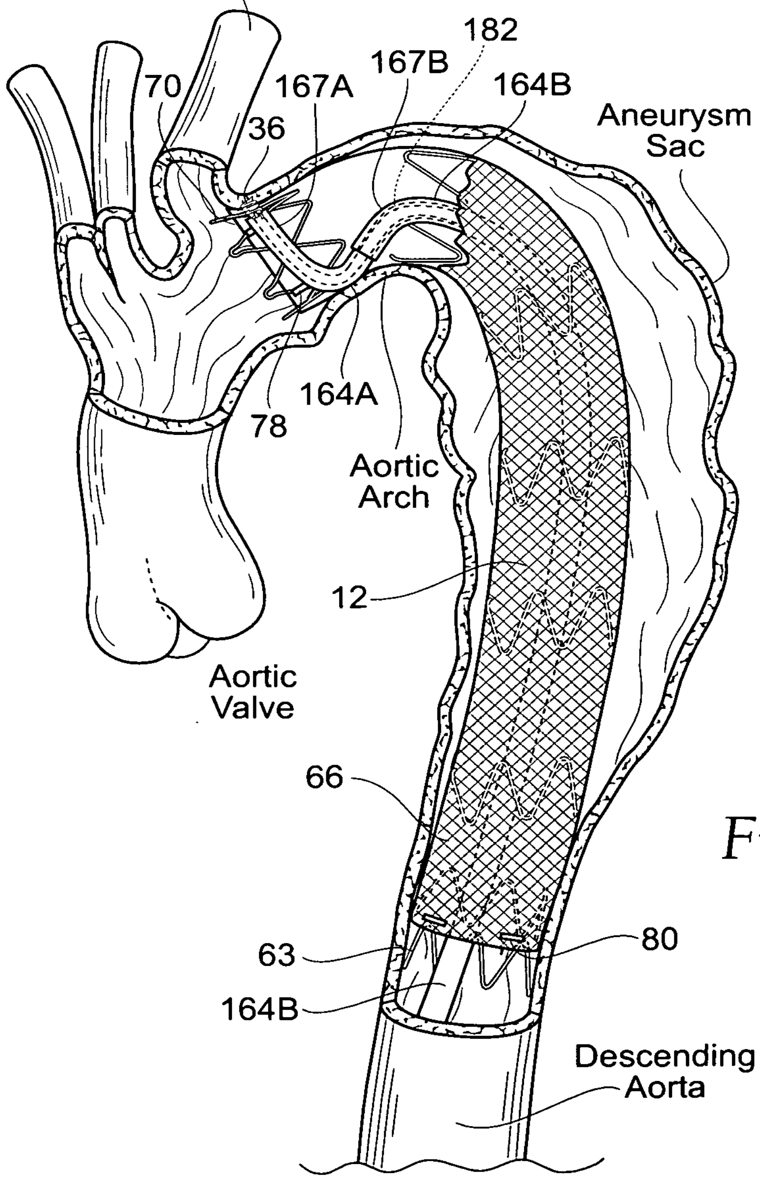


Fig. 16F

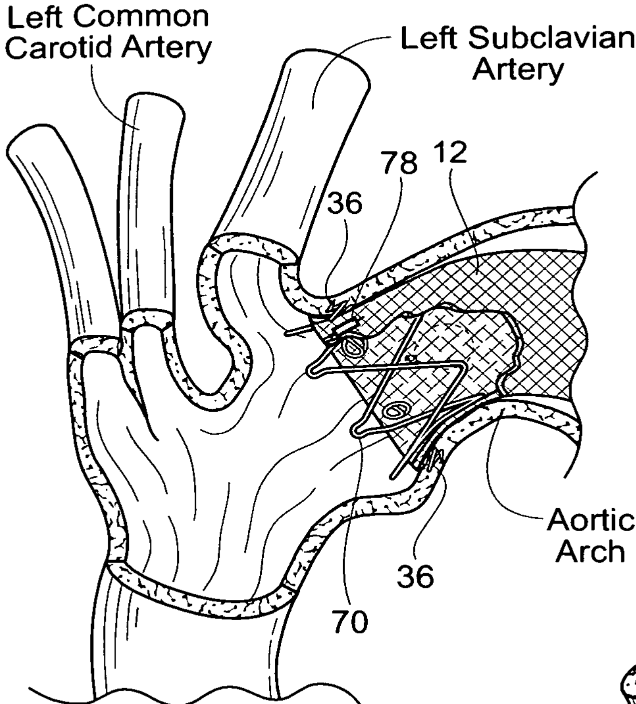


Fig. 16G

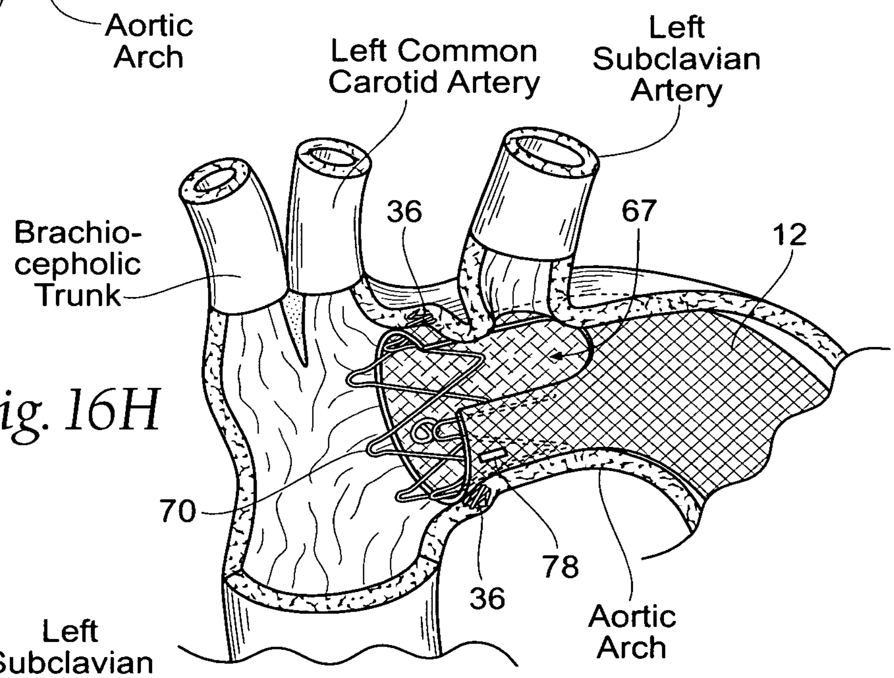


Fig. 16H

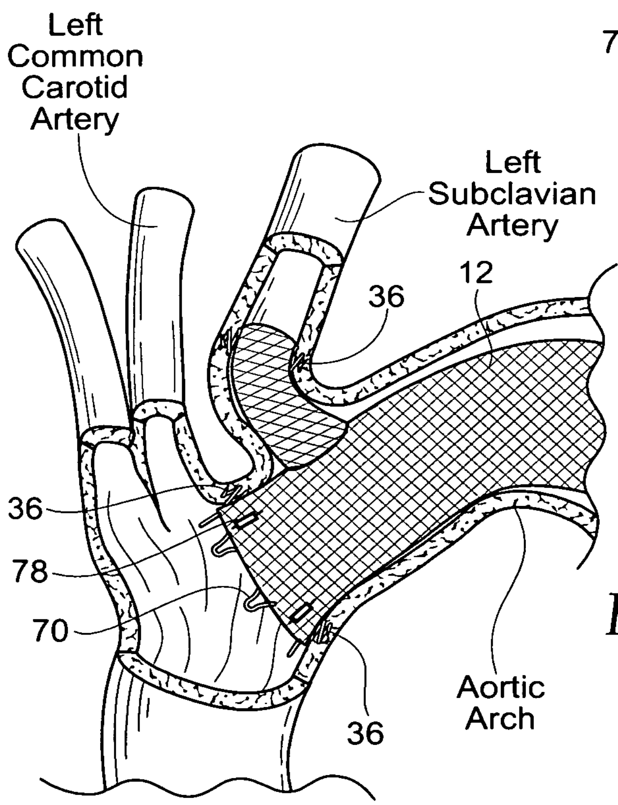


Fig. 16I

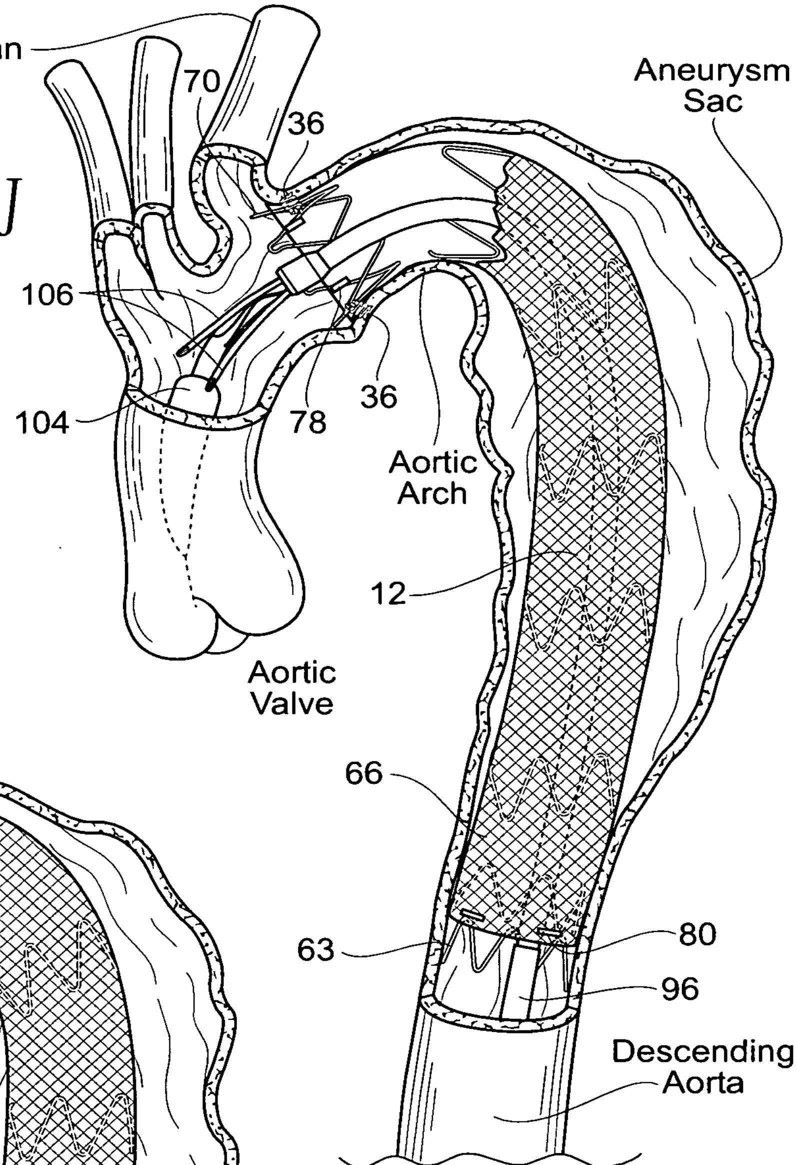


Fig. 16J

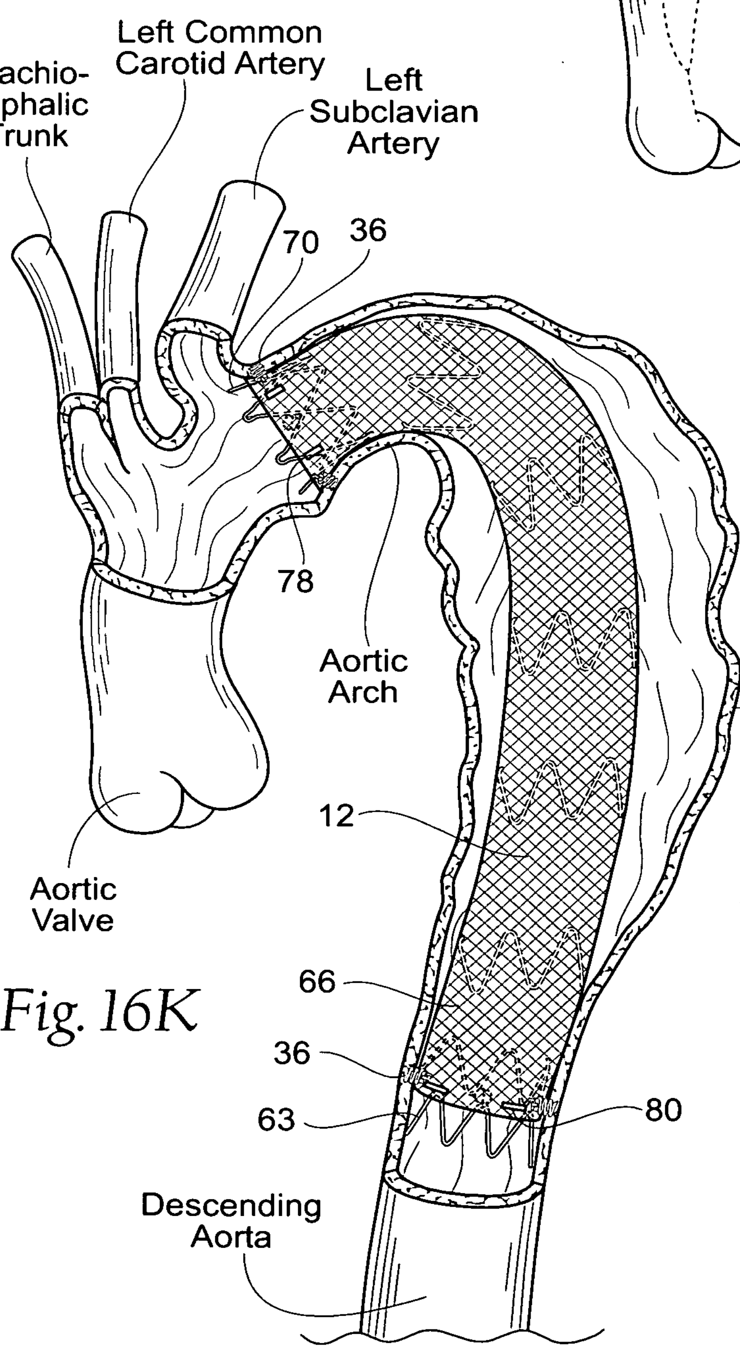
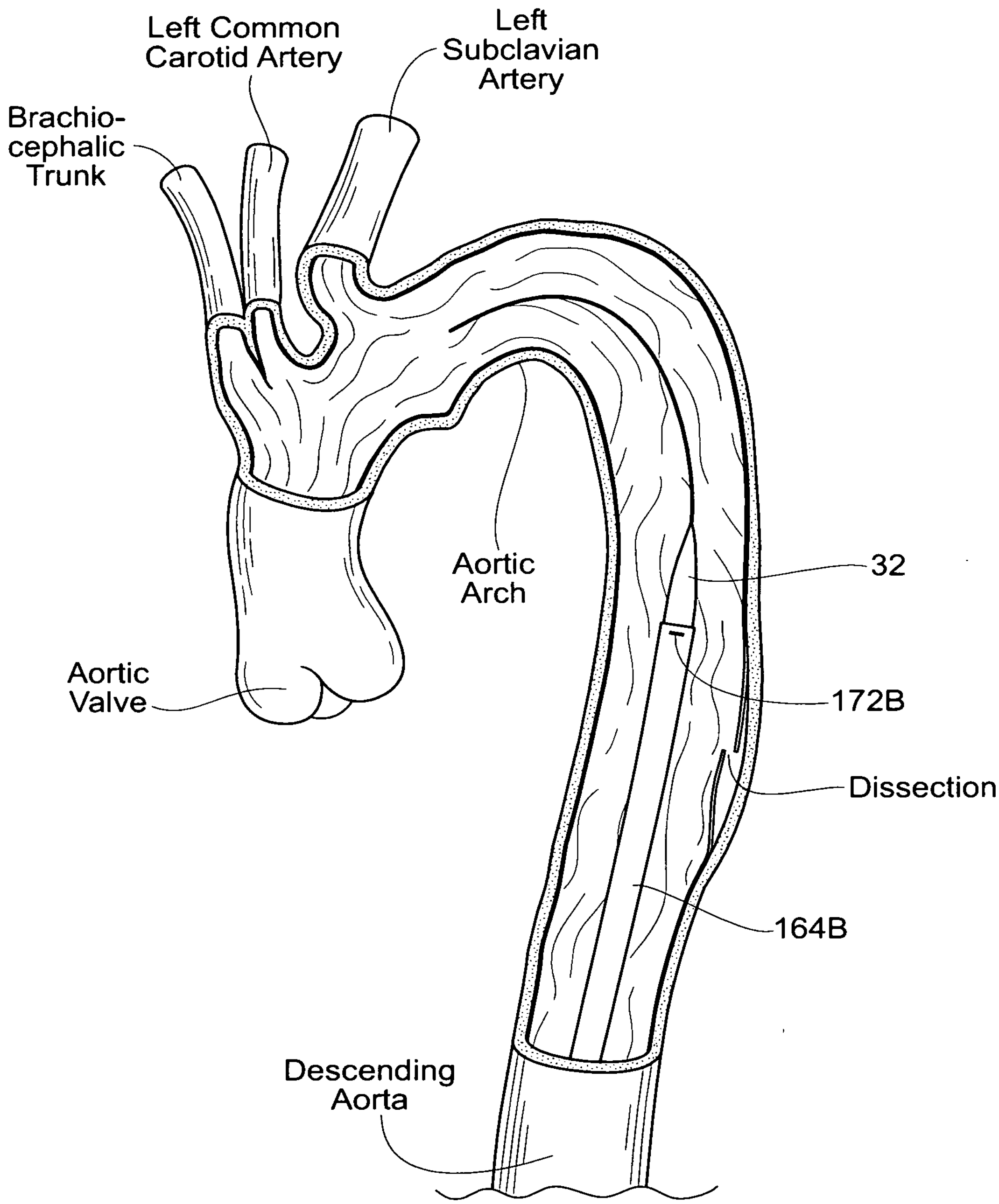


Fig. 16K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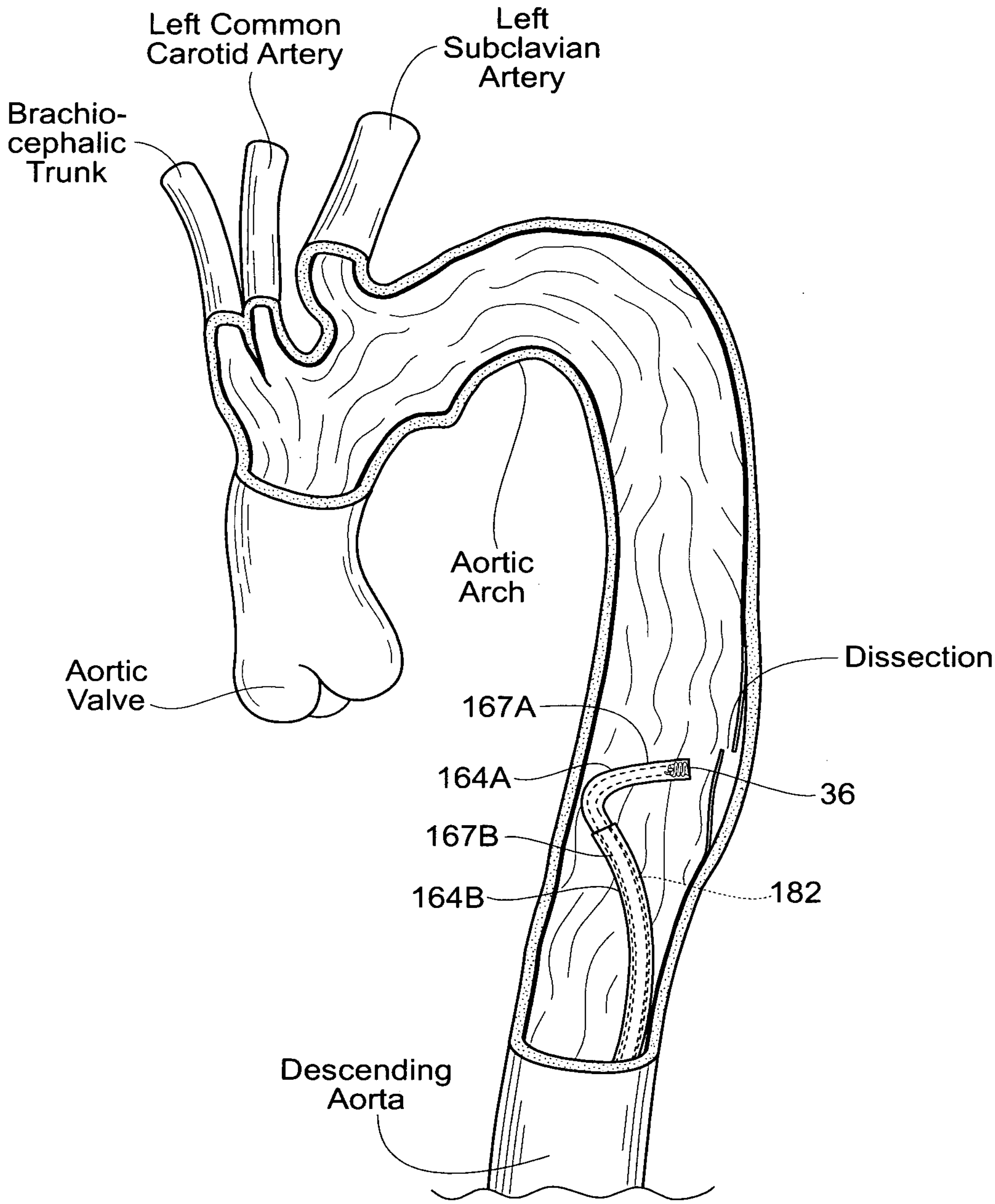
Carotid Artery
Left
Subclavian
Artery
Brachio-
cephalic
Trunk
Aortic
Arch
32
Aortic
Valve
172B
Dissection
164B
Descending
Aorta

Fig. 17A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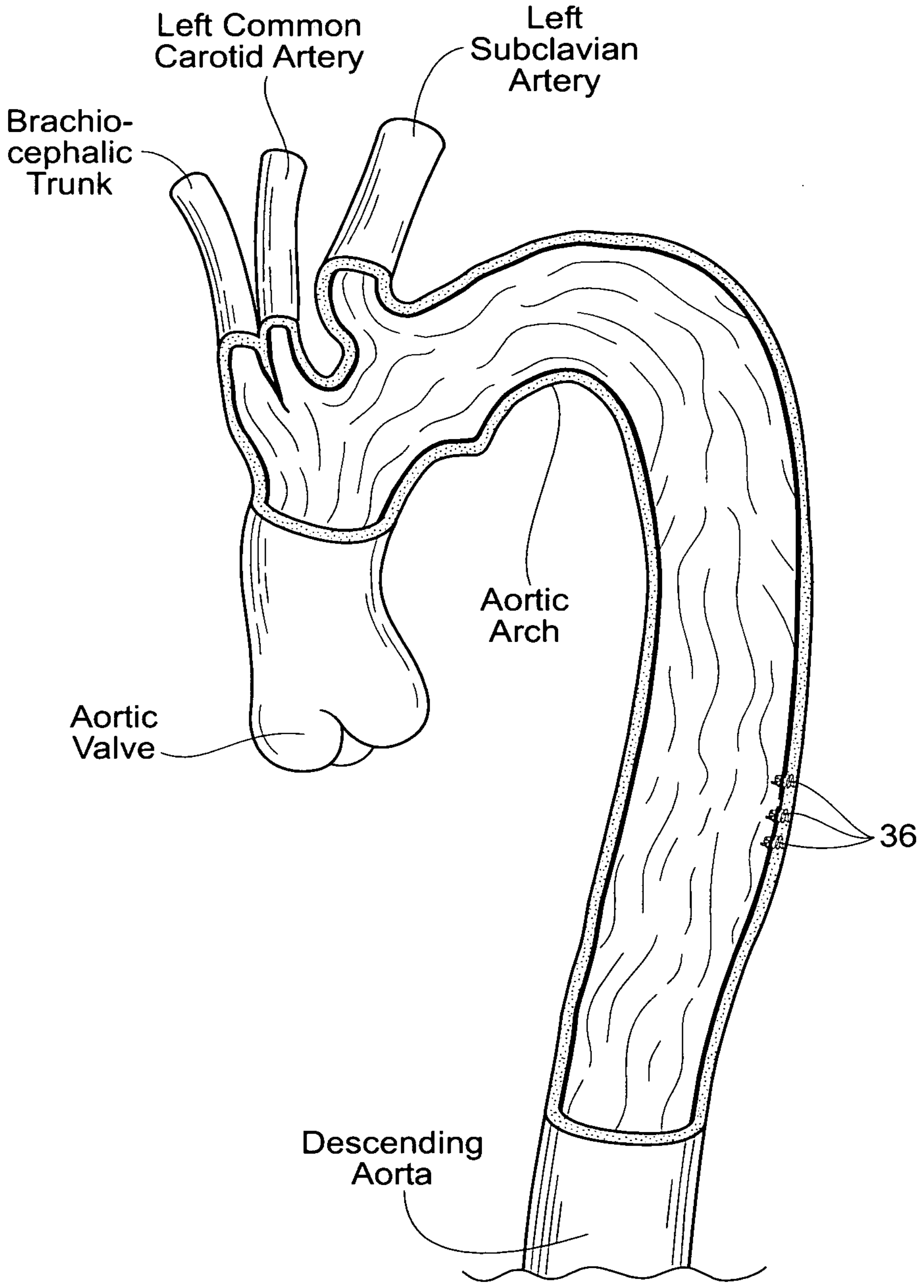
Left Subclavian Artery
Brachio-cephalic Trunk
Aortic Arch
Aortic Valve
Dissection
167A
164A
36
167B
164B
182
Descending Aorta

Fig. 17B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Carotid Artery
Left
Subclavian
Artery
Brachio-
cephalic
Trunk
Aortic
Arch
Aortic
Valve
36
Descending
Aorta

Fig. 17C

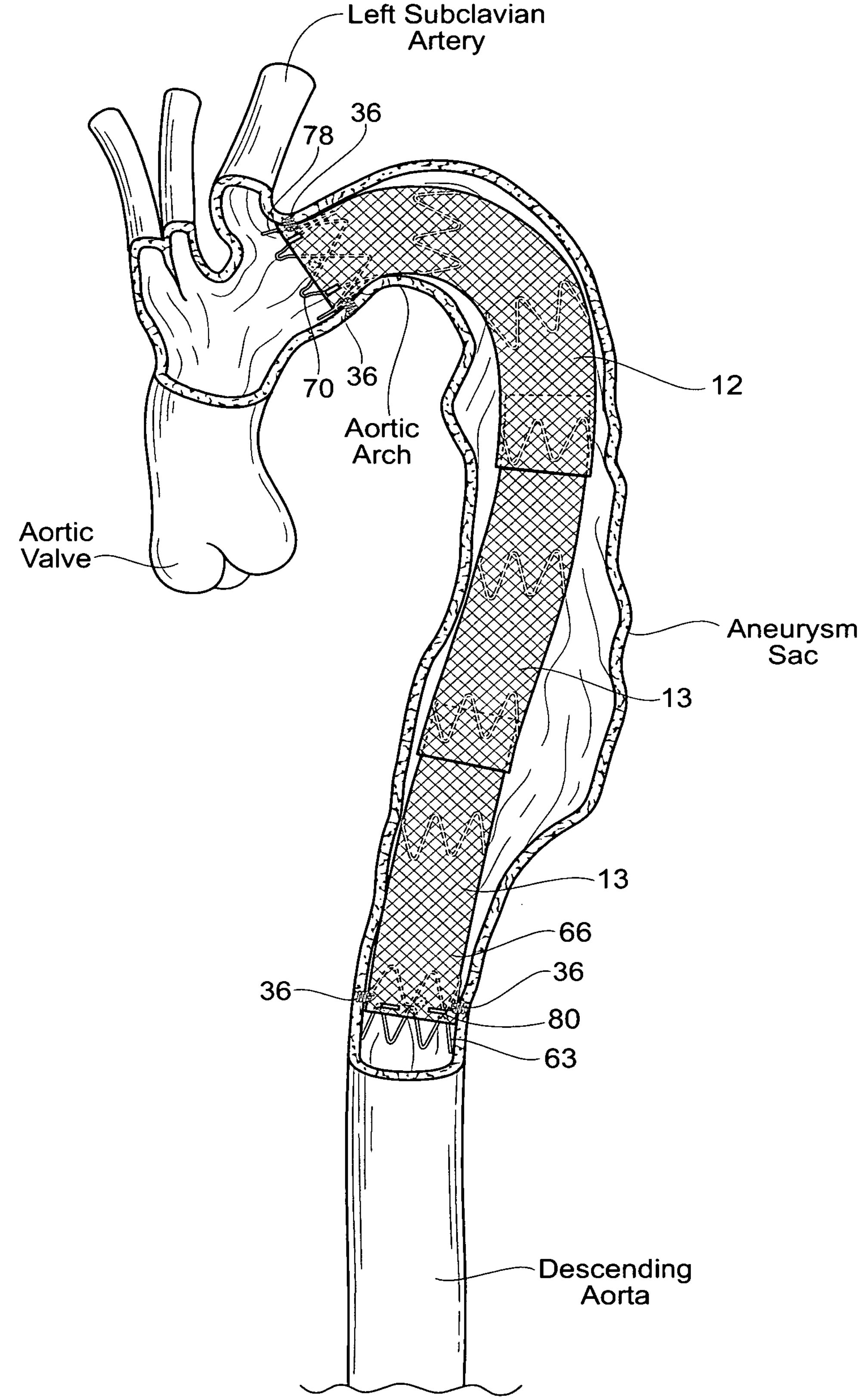
Left Subclavian Artery
36
78
36
70
12
Aortic Arch
Aortic Valve
Aneurysm Sac
13
13
66
36
36
80
63
Descending Aorta

Fig. 18A

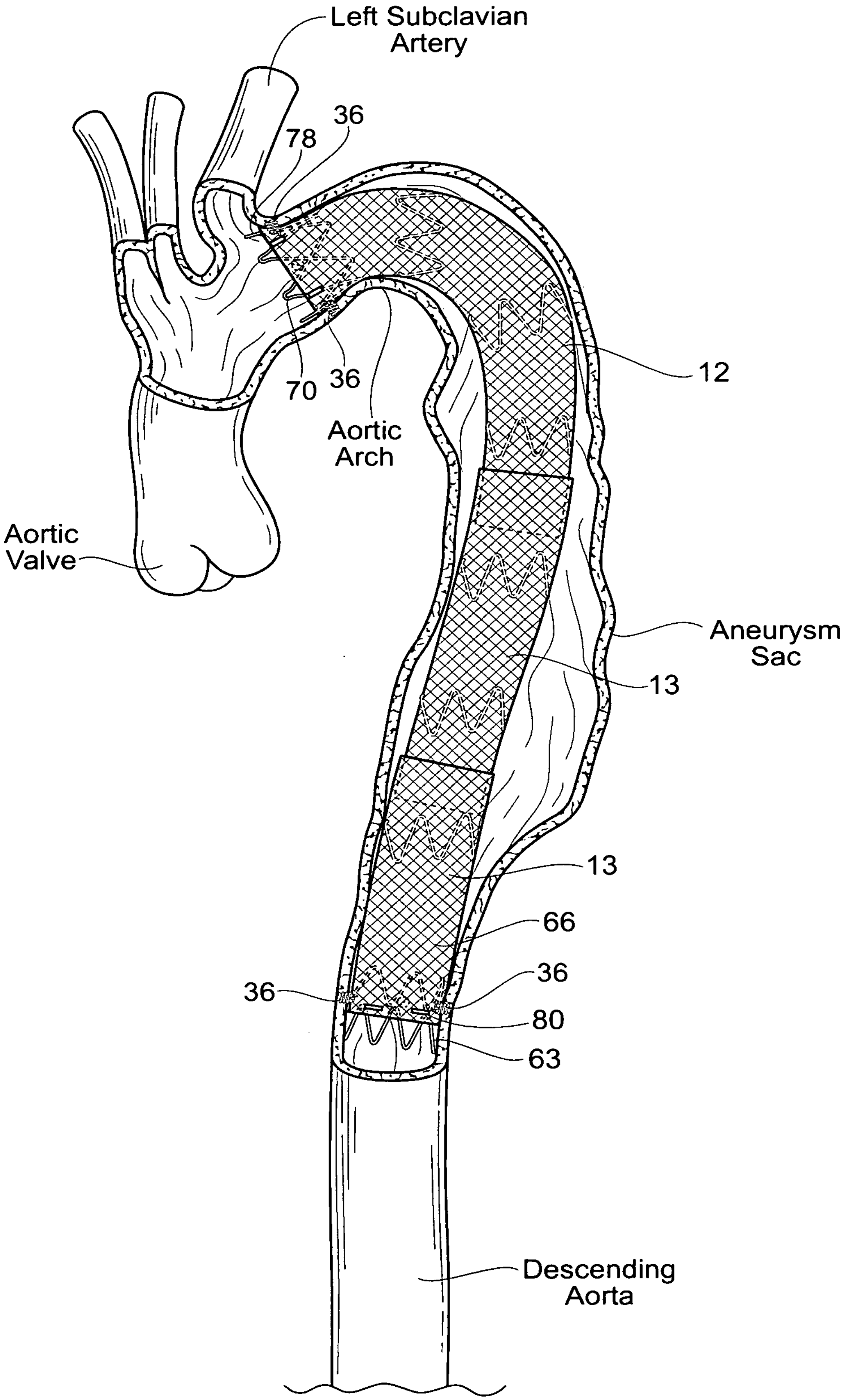
Left Subclavian Artery
36
78
12
70
36
Aortic Arch
Aortic Valve
Aneurysm Sac
13
13
66
36
36
80
63
Descending Aorta

Fig. 18B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 09/05604

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/06 (2009.01)
USPC - 623/1.11
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
623/1.11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
128/898, 604/96.01; 623/1.15, 1.2, 1.3, 1.32

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest, Google
Search Terms Used: Implant, lumen, steerable, catheter, guide, stapling or anchoring, fasteners, self-expanding or balloon expandable, bend , deflect.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2008/0065189 A1 (Bolduc) 13 March 2008 (13.03.2008), abstract, para [0033]-[0037], Figs. 9, 15.	1-22
Y	US 2007/0073389 A1 (Bolduc et al.) 29 March 2007 (29.03.2007), para [0008], [0054], [0115], [0161], Fig. 7A	1-22

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 December 2009 (01.12.2009)	11 DEC 2009

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12/288,034 16 October 2008 (16.10.2008) US

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(75) Inventor/Applicant *(for US only)*: **BOLDUC, Lee** [US/US]; 716 Grape Avenue, Sunnyvale, CA 94087 (US).

(74) Agents: **RYAN, Daniel, D.** et al.; P.O. Box 26618, Milwaukee, WI 53226-0618 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) Title: DEVICES, SYSTEMS, AND METHODS FOR ENDOVASCULAR STAPLE AND/OR PROSTHESIS DELIVERY AND IMPLANTATION

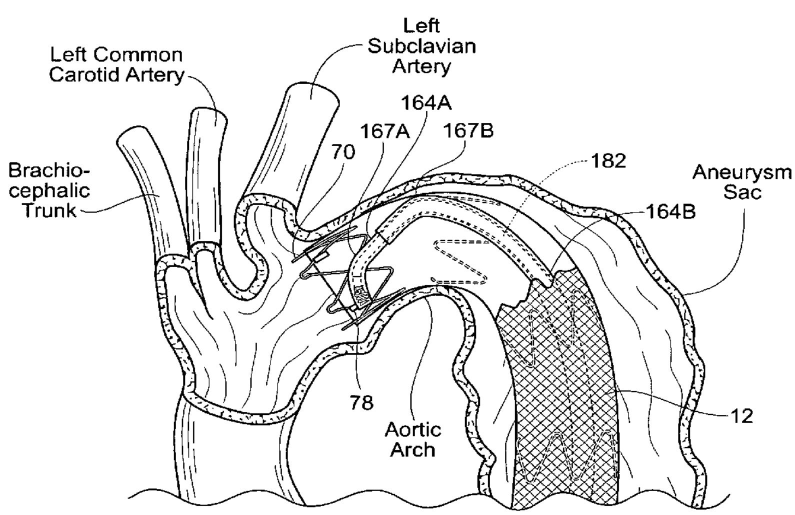


Fig. 13A

(57) Abstract: Devices, systems, and methods for implanting expandable prostheses in the body lumens rely on stapling or anchoring the prostheses with separately introduced fasteners. The prostheses may be self -expanding or balloon expandable, and may include a single lumen or more than one lumen. After initial placement, a stapling system is introduced within the expanded prosthesis to deploy a plurality of fasteners to at least one prosthesis end. The stapling system may apply a force- to the prosthesis to modify the shape of the prosthesis to conform to the shape of the vessel wall. The stapling system can be deflected in one or more distinct steerable segments. A lumen extension or lumens may be coupled to the prosthesis to extend the reach of the prosthesis within the implantation site. Fasteners may also be applied to the lumen extensions.

WO 2010/044856 A1

DEVICES, SYSTEMS, AND METHODS FOR ENDOVASCULAR STAPLE AND/OR PROSTHESIS DELIVERY AND IMPLANTATION

Related Applications

This application is a continuation-in-part of co-pending United Stated Patent Application Serial No. 11/488,305, filed July 18, 2006, and entitled "Endovascular Aneurysm Devices, Systems, and Methods."

This application is also a continuation-in-part of co-pending United Stated Patent Application Serial No. 11/255,116, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation."

This application is also a continuation-in-part of co-pending United States Patent Application No. 11/254,619, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Guiding an Operative Tool Into an Interior Body Region."

This application is also a continuation-in-part of co-pending United States Patent Application No. 11/633,724, filed December 5, 2006, entitled "Prosthesis Delivery Systems and Methods," which is a division of United States Patent Application Serial No. 10/692,283, (18379-PROV FOR) filed October 23, 2003 (now United States Patent 7,147,657), and entitled "Prosthesis Delivery Systems and Methods," which claims the benefit

of United States Provisional Patent Application Serial No. 60/488,753, filed July 21, 2003, and entitled "Endoprosthesis Delivery Systems and Methods."

This application also is a continuation-in-part of co-pending United Stated Patent Application Serial No. 10/786,465, filed February 25 2004, and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ."

This application is also a continuation-in-part of co-pending United States Patent Application 11/166,428, filed June 24, 2005, entitled "Multi-Lumen Prosthesis Systems and Methods," which is a division of United States Patent Application Serial No. 10/693,255, filed October 24, 2003 (now United States Patent 6,929,661), which claims the benefit of United States Provisional Patent Application Serial No. 60/489,011, filed July 21, 2003, and entitled "Bifurcated Prosthesis Systems and Methods."

This application also is a continuation-in-part of co-pending United Stated Patent Application Serial No. 10/307,226, filed November 29, 2002, and entitled "Intraluminal Prosthesis Attachment Systems and Methods."

This application is also a continuation-in-part of co-pending United States Patent Application Serial Number 10/669,881, filed September 24, 2003, entitled "Catheter-Based Fastener Implantation Apparatus and Methods with Implantation Force Resolution."

This application is also a continuation-in-part of co-pending United States Patent Application Serial No. 11/166,411, filed June 24, 2005, entitled "Endovascular Aneurysm Repair System," which is a division of United Stated Patent Application Serial No. 10/271,334, filed October 15, 2002 (now United States Patent No. 6,960,217), which claims the benefit of United States Provisional Patent Application Serial No. 60/333,937,

filed November 28, 2001, and entitled "Endovascular Aneurysm Repair System." Each of the preceding applications is incorporated herein by reference.

Field of the Invention

The invention relates generally to devices, systems, and methods for the delivery and implantation of an endovascular staple(s) and/or prosthesis to a targeted site within the body, e.g., for the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel.

Background of the Invention

The weakening of a vessel wall from damage or disease can lead to vessel dilatation and the formation of an aneurysm. Left untreated, an aneurysm can grow in size and may eventually rupture.

For example, aneurysms of the aorta occur in the abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation. Aneurysms can also occur in the tortuous thoracic region between the aortic arch and renal arteries. The rupture of an aortic aneurysm results in massive hemorrhaging and has a high rate of mortality.

Damage or disease of a vessel such as the aorta may also result in a dissection of the vessel wall. Aortic dissections are usually caused by a connective tissue disorder and/or high blood pressure. Left untreated, an aortic dissection can rupture or critically reduce blood flow to the heart, the brain, the spinal cord, the abdominal organs and the legs.

Open surgical replacement of a diseased or damaged section of vessel can eliminate the risk of vessel rupture. In this procedure, the diseased or damaged section of vessel is surgically removed and a prosthesis, made generally in either in a straight or bifurcated configuration, is installed and then permanently attached

and sealed to the ends of the native vessel by suture. The prostheses for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The prostheses are longitudinally unsupported so they can accommodate changes in the morphology of an aneurysm, dissection, and/or the native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co-morbidities.

Endovascular aneurysm and dissection repair has been introduced to overcome the problems associated with open surgical repair. The diseased or damaged section of the vessel is bridged with a vascular prosthesis, i.e., graft, which is placed intraluminally. Typically these prostheses for aortic aneurysms and dissections are delivered collapsed on a catheter through the femoral artery. These prostheses are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel.

Unlike open surgical repair of diseased or damaged sections of a vessel, such as an aortic aneurysm or an aortic dissection, intraluminally deployed prostheses are not sutured to the native vessel, but rely on either barbs or hooks extending from the stent, which penetrate into the native vessel during deployment and require a substantial area of healthy tissue to penetrate, and/or the radial expansion force of the stent itself is utilized to hold the prosthesis in position. These prosthesis attachment means do not provide the same level of attachment when compared to suture and can damage the native vessel upon deployment. In addition, in some areas the native vessel may include bends or turns, making it

difficult for one or both ends of the deployed prosthesis to expand, appose and seal the prosthesis to the vessel wall.

Accordingly, there is a need for improved prosthesis delivery and fastening devices, systems, and methods that deliver and fasten a staple(s) and/or a prosthetic graft within or to a body lumen, the prosthesis being able to adapt to changes in the vessel morphology and able to be deployed and fastened safely and without damage to the native vessel, including a tortuous vessel.

Summary of the Invention

The devices, systems, and methods for delivering and implanting radially expandable prostheses in the body lumens are described. In particular, the present invention provides improved devices, systems, and methods for implanting vascular prostheses into blood vessels, including both arterial and venous systems. In the exemplary embodiments, a variety of tools are used to place prostheses in vasculature to repair and/or reinforce aneurysms and/or dissections, particularly thoracic aortic aneurysms, and aortic dissections.

One aspect of the invention provides devices, systems, and methods including a system for modifying a prosthesis to conform to a vessel wall, the system comprising a catheter system sized and configured for introduction to a targeted site in the vessel, the catheter system adapted to apply a resolution of force to the prosthesis to modify the shape of the prosthesis to conform the shape of the prosthesis to the shape of the vessel wall, and the catheter system adapted to position a fastener in at least one region of the prosthesis to maintain the conformed shape of the prosthesis to the vessel wall. The catheter system may further include a lumen for passage of an endovascular device to the targeted site in the vessel.

In one embodiment, the catheter system is adapted to push against the prosthesis and against the vessel wall at the desired fastener position, and the catheter system is adapted to push against the generally opposite vessel wall for application of the resolution of force for fastener position.

In one embodiment, a fastening device may also be included, the fastening device sized and configured for introduction through the catheter system lumen to the targeted site in the vessel. The fastening device may include an actuator to deploy the fastener in at least one region of the prosthesis to maintain the conformed shape of the prosthesis to the vessel wall.

In one embodiment, the catheter system may comprise a steerable guide device. The steerable guide device may comprise a distal portion adapted to deflect in at least a first position. The steerable guide device may also comprise a distal portion adapted to deflect in at least a first position and a second position. The second position may be different than the first position. The steerable guide device may comprise a first steerable guide and a second steerable guide.

Another aspect of the invention provides devices, systems, and methods including a method of modifying a prosthesis to conform to a vessel wall. The method may include providing a catheter system sized and configured for introduction to a targeted site in the vessel, introducing into the vessel the catheter system, advancing the catheter system to the targeted site in the vessel, positioning a distal end of the catheter system against the prosthesis, positioning a distal portion of the catheter system against the prosthesis or vessel wall away from the distal end, continuing to advance the catheter system until the catheter system is applying a resolution of force to the prosthesis and modifying the

shape of the prosthesis and conforming the shape of the prosthesis to the vessel wall, and deploying a staple in at least one region of the prosthesis, the staple maintaining the conforming shape of the prosthesis to the vessel wall.

In one embodiment, the method may further include providing a staple applier sized and configured for introduction through a catheter system lumen to the targeted site in the vessel, the staple applier including an actuator for deploying the staple in at least one region of the prosthesis for maintaining the shape of the prosthesis to the vessel wall.

Another aspect of the invention provides devices, systems, and methods including a system for modifying a prosthesis to conform to a vessel wall comprising a steerable guide device sized and configured for introduction to a targeted site in the vessel, the steerable guide device including a lumen for passage of an endovascular device to the targeted site in the vessel, a fastening device sized and configured for introduction through the steerable guide device lumen to the targeted site in the vessel, the steerable guide device adapted to apply a resolution of force to the prosthesis to modify the shape of the prosthesis to conform the shape of the prosthesis to the vessel wall, and the fastening device including an actuator to deploy a fastener in at least one region of the prosthesis to maintain the conformed shape of the prosthesis to the vessel wall.

In yet another aspect of the invention, devices, systems, and methods include a method of modifying a prosthesis to conform to a vessel wall comprising providing a steerable guide device sized and configured for introduction to a targeted site in the vessel, the steerable guide device including a lumen for passage of

an endovascular device to the targeted site in the vessel, providing a staple applier sized and configured for introduction through the steerable guide device lumen to the targeted site in the vessel, the staple applier including an actuator for deploying a staple in at least one region of the prosthesis for maintaining the shape of the prosthesis to the vessel wall, introducing into the vessel the steerable guide device, advancing the steerable guide device to the targeted site in the vessel, positioning a distal end of the steerable guide device against the prosthesis, positioning a distal portion of the steerable guide device against the prosthesis or vessel wall away from the distal end, advancing the staple applier through the steerable guide device lumen until the staple applier emerges from the distal end of the steerable guide device and contacts the prosthesis, continuing to advance the staple applier until the staple applier is applying a resolution of force to the prosthesis and modifying the shape of the prosthesis and conforming the shape of the prosthesis to the vessel wall, and deploying a staple in at least one region of the prosthesis, the staple maintaining the conforming shape of the prosthesis to the vessel wall.

In yet another aspect of the invention, devices, systems, and methods include a method of modifying a prosthesis to conform to a vessel wall comprising providing a prosthesis adapted for endovascular delivery and implantation, the prosthesis including a delivery shape and a deployed shape, delivering the prosthesis to a target site, deploying the prosthesis at the target site causing the prosthesis to change shape from the delivery shape to the deployed shape, and manipulating the prosthesis by implanting a fastener through the prosthesis causing the prosthesis to change shape from the deployed shape to an implanted shape different from

the deployed shape.

The fastener may be implanted through the prosthesis and into tissue. The implanted shape conforms to a shape of the target site. The target site may comprise a tortuous vessel.

In one embodiment, the prosthesis may further include a proximal portion and a distal portion, and manipulating the prosthesis includes manipulating the proximal portion of the prosthesis by implanting a fastener through the proximal portion of the prosthesis causing the proximal portion of the prosthesis to change shape from the deployed shape to an implanted shape different from the deployed shape. The prosthesis distal portion may maintain its deployed shape and is not manipulated to change shape from its deployed shape to an implanted shape.

In another aspect of the invention, devices, systems, and methods include a catheter system comprising a catheter system sized and configured for introduction to a targeted site in the vessel, the catheter system adapted to apply a resolution of force to a prosthesis to modify the shape of the prosthesis to conform the shape of the prosthesis to the shape of the vessel wall, the catheter system adapted to position a fastener in at least one region of the prosthesis to maintain the conformed shape of the prosthesis to the vessel wall, and instructions for use describing the use of the catheter system, the instructions comprising the operations of introducing into the vessel the catheter system, advancing the catheter system to the targeted site in the vessel, positioning a distal end of the catheter system against the prosthesis, positioning a distal portion of the catheter system against the prosthesis or vessel wall away from the distal end, continuing to advance the catheter system until the catheter system is applying a

resolution of force to the prosthesis and modifying the shape of the prosthesis and conforming the shape of the prosthesis to the vessel wall, and deploying a staple in at least one region of the prosthesis, the staple maintaining the conforming shape of the prosthesis to the vessel wall.

In one embodiment, the catheter system may be adapted to push against the prosthesis and against the vessel wall at the desired fastener position, and the catheter system is adapted to push against the generally opposite vessel wall for application of the resolution of force for fastener position.

Brief Description of the Drawings

Fig. 1 is a perspective view of a healthy aorta showing the extent of the aorta from the aortic root, through the aortic arch, the descending thoracic aorta, and to the abdominal aorta and aortic bifurcation.

Figs. 2A to 2C are perspective views of diseased aortas, showing the extent to which aneurysms may deform the aorta.

Figs. 3A and 3B are perspective views of diseased aortas, showing aortic dissections.

Fig. 4 is a view of the components of a system for repairing an endovascular aneurysm.

Fig. 5 is a view of the components of the system shown in Fig. 4 consolidated for use in a multiple piece kit, along with instructions for their use.

Fig. 6A is a side view of one embodiment of an endovascular graft that forms a part of the system shown in Fig. 4, the supported graft including a most proximal stent extending beyond the proximal edge of the graft.

Fig. 6B is a side view of an additional embodiment of an endovascular graft that forms a part of the system shown in Fig. 4, the unsupported graft including a distal stent and a most proximal stent not extending beyond the

proximal edge of the graft.

Fig. 6C is a side view of an additional embodiment of an endovascular graft shown in Fig. 6B, the unsupported graft including a most proximal stent not extending beyond the proximal edge of the graft, and without a distal stent.

Fig. 6D is a side view of an additional embodiment of an endovascular graft that forms a part of the system shown in Fig. 4, the unsupported graft including a proximal portion with a first diameter, and a tapered portion extending to a distal portion have a second diameter smaller than the first diameter.

Fig. 6E is a side view of an additional embodiment of an endovascular graft shown in Fig. 6D, the unsupported graft including a most proximal stent not extending beyond the proximal edge of the graft, and without a distal stent.

Fig. 6F is a side view of an additional embodiment of an endovascular graft that forms a part of the system shown in Fig. 4, the unsupported graft including a curved portion adapted for placement in a tortuous vessel, and including a most proximal stent not extending beyond the proximal edge of the graft, and without a distal stent.

Fig. 6G is a side view of an additional embodiment of an endovascular graft that forms a part of the system shown in Fig. 4, the supported graft including a graft opening, the graft adapted to allow positioning of the proximal portion of the graft proximal to a branch artery (e.g., the left subclavian artery where healthy tissue may be present for securing the graft, and maintaining fluid flow communication to the branch artery.

Fig. 6H is a close-up view of the opened or fenestrated portion of the endovascular graft shown in Fig. 6G.

Fig. 6I is a perspective view of an additional

embodiment of endovascular graft that forms a part of the system shown in Fig. 4, the branched graft includes a small ancillary branch protruding from the side of the graft, the branch 68 adapted to align with a vessel branch.

Fig. 6J is a view of an additional embodiment of endovascular graft that forms a part of the system shown in Fig. 4, the graft including areas adapted for preferential bending/folding, allowing the graft to better conform to angled or tortuous anatomy.

Fig. 6K is a view of the graft shown in Fig. 6J, showing the graft implanted in a tortuous vessel.

Fig. 6L is a view of the graft shown in Fig. 6J, showing the ability of the graft to bend/fold in a multi-curved configuration.

Fig. 6M is a view of the graft shown in Fig. 6J, showing the graft in a compressed configuration, the graft having the ability to be processed to bend/fold at predefined locations.

Fig. 7A is an anatomic view of a representative graft assembly implanted within a descending thoracic aortic aneurysm (TAA).

Fig. 7B is an anatomic view of a representative graft assembly implanted within a descending thoracic aorta, the graft positioned to repair an aortic dissection.

Fig. 8A is a view of the delivery system for the endovascular graft, which forms a part of the system shown in Fig. 4.

Figs. 8B and 8C are perspective views of the top and bottom of the control handle of the delivery system shown in Fig. 8A.

Fig. 8D is an enlarged perspective view of the distal end of the delivery system shown in Fig. 8A, with parts broken away to show the attachment of a supported

endovascular graft to the delivery system and the release wire and/or wires and jacket controls that are coupled to the handle to affect a controlled stepwise release of the endovascular graft from the delivery system.

Fig. 8E is a view of the distal end of the delivery system showing the retracted and advanced positions of the slidable release jacket, with an unsupported graft attached to the delivery system.

Fig. 8F is a view of the distal end of the delivery system showing the retracted and advanced positions of the slidable release jacket as shown in Fig. 8E, and showing a supported graft attached to the delivery system.

Fig. 8G is a view of the distal end of the delivery system showing the retracted and advanced positions of the slidable release jacket as shown in Fig. 8E, and showing an alternative delivery system without stabilizing arms.

Fig. 9 is an enlarged view of a hemostatic seal assembly within the handle of the delivery system, showing the passage of the release wires through the seal assembly between the control mechanisms and the distal end of the delivery system (as shown in Fig. 8D).

Fig. 10A is a perspective view of the first steerable endovascular guide, the second steerable endovascular guide, and the obturator, which make up a steerable endovascular guide system (a two segment guide system is shown) that form a part of the system shown in Fig. 4.

Fig. 10B is a perspective view of the guide tube from the first steerable endovascular guide nested within the second steerable endovascular guide, the nested system adapted to guide the staple applier through at least one resolved angle and to apply an apposition force to conform the shape of the endovascular graft to be

secured to the vessel wall.

Fig. 10C is an enlarged view of the handle of the first steerable endovascular guide shown in Fig. 10A.

Fig. 10D is a view of an alternative embodiment of a steerable endovascular guide shown in Fig. 10B, showing the steerable endovascular guide as a single guide device incorporating the features of the first steerable guide and the second steerable guide.

Fig. 10E is a view of an additional alternative embodiment of a steerable endovascular guide, showing the steerable endovascular guide as a single handle guide device with a single steerable guide tube adapted for steering in multiple directions.

Fig. 11A is a view of an endovascular fastener or staple that forms a part of the system shown in Fig. 4.

Fig. 11B is a view of a cassette to hold a plurality of endovascular fasteners, as shown in Fig. 11A, and to present the fasteners for loading in the staple applier, which also forms a part of the system shown in Fig. 4.

Fig. 12A is a view of a fastener applier for implanting a fastener as shown in Fig. 11A, which forms a part of the system shown in Fig. 4.

Fig. 12B is an enlarged view of the handle of the fastener applier shown in Fig. 12A, and showing the controls available to the user.

Fig. 12C is a view showing the manipulation of the fastener applier shown in Fig. 12A in loading a fastener from the cassette shown in Fig. 11B.

Fig. 13A is an anatomic view showing the driven member at the distal end of the fastener applier (and positioned within the catheter of the two segment steerable guide system) prior to being driven to implant a fastener in a graft and adjacent tissue, to secure the position of the graft, and showing the two segment steerable guide system adapted to guide the fastener

applier through at least one angle to reach tortuous locations for fastener implant.

Figs. 13B and 13C are anatomic views as shown in Fig. 13A, showing the fastener applier positioned within the two segment steerable guide system, the steerable guide system being used to apply an apposition force to the endovascular graft to deflect a portion of the graft against the vessel wall where the graft may not naturally lay flat, modifying the shape of the endovascular graft to conform to the vessel wall, and then implanting a fastener in the graft and adjacent tissue, to secure the position of the graft.

Fig. 14A is a view showing a fastener applier of a type shown in Fig. 12A, which includes indicia visible to a naked eye.

Fig. 14B is a view showing the fastener applier shown in Fig. 14A nested within the two segment steerable endovascular guide system of a type shown in Fig. 10B, showing how the indicia, which is visible to a naked eye, marks when the driven member rests at a desired distance within the steerable guide system just short of the terminus of the guide tube of the first steerable guide and therefore out of contact with tissue.

Fig. 14C is a close-up view showing the distal end of the two segment steerable guide system when the indicia visible at the proximal portion of the applier catheter marks when the actuated member rests at a desired distance within the first guide tube short of the terminus of the first guide tube and therefore out of contact with tissue.

Fig. 15A is a schematic view of the motor control functions of a representative control circuit for the fastener applier shown in Fig. 12A.

Fig. 15B is a schematic flow diagram of the operational states of the control circuit shown in Fig.

15A.

Figs. 16A to 16K are anatomic views of manipulation of the components of the system shown in Fig. 4 in placing a prosthesis in a descending thoracic aortic aneurysm, which manipulations can be incorporated within an instruction for use associated with a kit like that shown in Fig. 5.

Figs. 17A to 17C are anatomic views of manipulation of components of the system shown in Fig. 4 in repairing an aortic dissection in the descending thoracic aorta using staples and without a graft, which manipulations can be incorporated within an instruction for use associated with a kit of components like that shown in Fig. 5.

Figs 18A and 18B are anatomic views showing an alternative graft assembly comprising three graft assemblies nested together to extend the length of the implanted graft.

Description of the Preferred Embodiment

Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention which may be embodied in other specific structures. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

This specification discloses various catheter-based devices, systems, and methods for delivering and implanting staples and prostheses, including radially expandable prostheses in the body lumens. For example, the various aspects of the invention have application in procedures requiring the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel. The devices, systems, and methods that embody

features of the invention are also adaptable for use with systems and surgical techniques that are not necessarily catheter-based.

The devices, systems, and methods are particularly well suited for treating aortic dissections and aneurysms of the aorta, including those that occur in the thoracic region between the aortic arch and renal arteries, as well as aneurysms that also occur in the abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation. For this reason, the devices, systems, and methods will be described in this context. Still, it should be appreciated that the disclosed devices, systems, and methods are applicable for use in treating other dysfunctions elsewhere in the body, which are not necessarily aorta-related.

When referring to a prosthesis, i.e., an endovascular graft or its components that are intended to be implanted in a vessel or body organ, the terms "proximal" and "distal" will be used to describe the relation or orientation of the graft with respect to the heart after implantation. Therefore, the term "proximal" will be used to describe a relation or orientation of the graft that, when implanted, is toward the heart, and the term "distal" will be used to describe a position or orientation of the graft that, when implanted, is away from the heart, i.e., toward the feet.

When referring to implantation apparatus or devices that are manipulated by a physician or operator in order to implant the endovascular graft or its components, the terms "proximal" and "distal" will be used to describe the relation or orientation of the apparatus or device with respect to the operator as it is used. Therefore, the term "proximal" will be used to describe a relation or orientation of the apparatus or device that, when in use, is positioned toward the operator (i.e., at the

handle end of the device), and the term "distal" will be used to describe a position or orientation of the apparatus or device that, when in use, is positioned away from the operator (i.e., at the other end of a catheter or the like away from the handle).

I. Aortic Abnormalities

A healthy aorta, the body's largest artery, has a general shape like the handle portion of a walking cane (see Fig. 1). The short length of the curved handle comes out of the heart and curls through the aortic arch. Multiple smaller arteries branch off at the aortic arch to serve the head and arms. The aorta continues to descend through the chest cavity into the abdomen and separates to provide blood to the abdominal organs and both legs. Various abnormalities may affect the aorta, most of which are considered potentially life-threatening. Prevalent aortic abnormalities include aortic aneurysms and aortic dissections, as non-limiting examples.

Aneurysms may affect one or more segments of the thoracic aorta, including the ascending aorta, the arch, and the descending thoracic aorta. A thoracic aortic aneurysm (TAA) can be described as an expanded (bulging) section(s) of the wall of the aorta, and is considered a life-threatening condition. Thoracic aortic aneurysms of any size can cause significant short- and long-term mortality due to rupture and dissection. Figs. 2A, 2B, and 2C show examples of aortas having diseased tissues and difficult cases where the left subclavian artery ostium is distal to the aortic arch. Relative positions of the aneurysmal tissues in the tortuous aortic arch can be seen, as can and relationship to the brachiocephalic trunk, left common carotid artery, and the left subclavian artery. Often the left subclavian artery provides a landmark for positioning of an endovascular

graft (to be described in greater detail below).

Common causes of a thoracic aortic aneurysm include hardening of the arteries (atherosclerosis), degeneration of the media of the aortic wall, as well as from local hemodynamic forces. Additional risk factors include various connective tissue disorders such as Marfan syndrome, previous dissection of the aorta, and trauma such as falls or motor vehicle accidents. They also sometimes occur in people who have bicuspid aortic valves.

An aortic dissection is a perforation or tear in the lining of the aorta. The tear allows blood to flow between the layers of the aortic wall, with the force of the blood forcing the layers of the wall apart. Figs. 3A and 3B show views of aortic dissections. An aortic dissection is a medical emergency and can quickly lead to death. If the dissection tears the aortic wall completely open, massive and rapid blood loss occurs.

The tearing of the inner lining of the aorta causes the blood to separate along the wall of the artery. This generally causes two channels in the vessel, with one channel referred to as the true channel and the other channel referred to as the false channel. As can be seen in Figs. 3A and 3B, the tear allows the blood to create the false channel. With each heartbeat, the artery may progressively tear more and more with blood propagating down the false channel blocking off the true channel and the flow of blood to some or all of the branches of the aorta.

Aortic dissections can be classified by the Stanford method into a type A or type B depending on the location and the extent of the dissection. Type A dissection, or proximal dissection, involves the ascending aorta and aortic arch, and may or may not involve the descending aorta. Type B dissection, or distal dissection, usually

begins just distal to the ostium of the left subclavian artery, extending distally into the descending and abdominal aorta. If left untreated, the risk of death from aortic dissection can reach 30 percent within fifteen minutes after onset of symptoms and 75 percent by one week.

II. SYSTEM OVERVIEW

Aortic abnormalities, such as thoracic aortic aneurysms and aortic dissections with the appropriate anatomy, may now be repaired by the implantation of an endovascular prosthesis or graft. The implantation of staples alone may also be used for the repair of aortic dissections. Fig. 4 shows an exemplary system 10 for repairing an aortic abnormality. By way of example, the system 10 and/or components of the system are well suited for the repair of a descending thoracic aortic aneurysm and/or an aortic dissection, and will be described in this context. The system 10 comprises three primary components 12, 14, and 16.

The first component comprises an endovascular prosthesis or graft assembly 12. In use, the endovascular graft 12 is placed within a vessel at the site of the aortic abnormality. The endovascular graft 12 serves to exclude a portion of the vascular system from blood flow and blood pressure. In order to obtain exclusion of a portion of the vascular system, the endovascular graft must be sealed against the vascular wall, which requires apposition between the endovascular graft 12 and the vascular wall. The endovascular graft 12 must also be prevented from moving or migrating from its deployed position within the vascular system.

In the illustrated embodiments, the endovascular graft 12 is placed and secured within the aortic arch, e.g., at or near the left subclavian artery and extends past the site of the aneurysm and into the descending

aorta (see Fig. 7A). Fig. 7B shows the endovascular graft 12 placed and secured within the descending aorta and extending past the site of a dissection. Additional embodiments of a graft assembly 12 are shown in Figs. 6B through 6M.

The second component 14 comprises an endovascular delivery system for introducing and deploying the endovascular graft 12 using an endovascular approach. In the illustrated embodiment, in which the endovascular graft 12 comprises a single lumen body, a single endograft delivery component 24 may be provided. In alternative embodiments incorporating modular endovascular graft components, there may be individual corresponding endograft delivery components provided.

The third component 16 comprises an endovascular stapling system. In one embodiment, the endovascular stapling system 16 may be used to attach one or more regions of the endovascular graft 12 to the vessel wall with one or more endovascular staples. The endovascular stapling system 16 may also be used for implanting one or more endovascular staples without including an endovascular graft 12, the endovascular staples serving to close the entrance of the dissection to blood flow.

In one embodiment, the endovascular stapling system 16 comprises a steerable endovascular guide system 30 comprising a first steerable guide 30A and a second steerable guide 30B, an obturator 32, a cassette 34 holding a plurality of endovascular staples 36, and an endovascular fastening device, i.e., a staple applier 38. In an alternative embodiment, the two steerable guide catheters 30A and 30B may be combined into one operational handle with two steerable guide catheters. The steerable endovascular guide system 30 is sized and configured to provide at least one angle, rotational positioning, and relative positioning (axially) between

the two guide catheters and preferably two or more angles with rotational positioning and relative positioning between the two guide catheters.

In use, the steerable endovascular guide system 30 establishes an endovascular path to the targeted site where the endovascular graft 12 has been positioned, and may be partially or fully deployed. The steerable endovascular guide system 30 is adapted to be manipulated by flexure and rotation in at least one direction or angle to provide the staple applier 38 access to successive sites, including difficult to reach sites due to tortuous anatomy of the vessel. The endovascular staple applier 38, carrying one or more endovascular staples 36, is guided by the two segment (30A and 30B) steerable endovascular guide system 30 to the successive sites. Once positioned, individual endovascular staples 36 are implanted, to penetrate the endovascular graft 12 (if used) and adjacent vessel wall. The endovascular staple applier 38 is actuated to implant individual endovascular staples 36 into selected region or regions of the endovascular graft 12 and adjacent vessel wall, to attach the endovascular graft 12 to the vessel wall.

The stapling system is adapted to apply an apposition force, i.e., resolution of force, to the endovascular graft 12 to modify the shape or form of the endovascular graft to conform to the shape of the vessel wall. This resolution of force can be utilized to deflect a portion or portions of the endovascular graft against the vessel wall to implant an endovascular staple, i.e., a fastener. After the conformance is obtained, a fastener or fasteners are implanted through the endovascular graft 12 and into the vessel wall. The fastener(s) maintain the shape of the modified configuration of the endovascular graft. This modified shape enables the endovascular graft 12 to obtain apposition between the graft 12 and the

tortuous wall(s) of the vessel, and to exclude a portion of the vascular system.

III. SYSTEM KIT

As Fig. 5 shows, the various tools and devices as just described, comprising the system 10, can be consolidated for use in a multiple piece functional kit 40. It is to be appreciated that the various tools and devices are not necessarily shown to scale.

The kit 40 can take various forms. In the illustrated embodiment, the kit 40 comprises an assemblage of individual packages 42, 48, 50, 52, 54, and 56, each comprising a sterile, packaged assembly. One or more of the packages may include an interior tray or card made, e.g., from die cut cardboard, plastic sheet, or thermo-formed plastic material, which hold the contents. The kit 40 also preferably includes instructions or directions 58 for using the contents of the packages to carry out a desired procedure. A desired procedure using the contents of the kit 40 shown in Fig. 5 will be described in greater detail later.

The instructions for use 58 can, of course vary. The instructions for use 58 can be physically present in one or more of the packages, but can also be supplied separately. The instructions for use 58 can be embodied in separate instruction manuals, or in video or audio recordings. The instructions for use 58 can also be available through an internet web page.

A. The Component Packages

The arrangement and contents of the packages can vary. For example, as shown in Fig. 5, the kit 40 comprises six packages 42, 48, 50, 52, 54, and 56, and instructions 58. Three of these packages 42, 48, and 50 provide the main components of the endovascular repair system 10 as described. The remaining packages 52, 54, and 56 provide ancillary components used in the

deployment of the system 10, e.g., conventional vascular access sheaths (in package 52); conventional 0.035 inch guide wires (in package 54); and bags containing heparinized saline for catheter flushing and contrast for angiography (in package 56).

In package 42, the endovascular graft 12 is preloaded into the endograft delivery component 24. Housed within the package 42, the endovascular graft 12 and the corresponding delivery component 24 for the endovascular graft are supplied sterile to the user.

As further shown in Fig. 5, the kit 40 comprises an additional package 50 that provides the two segment (30A and 30B) steerable endovascular guide system 30 and at least one associated component; namely, the obturator 32. As previously described, the steerable endovascular guide system 30 may also comprise a single device having the combined features of the two separate catheters. The kit 40 also comprises an additional package 48 that provides the endovascular staple applier 38 and at least one associated component; namely, a cassette 34 holding a plurality of endovascular staples 36. Housed within the packages 48 and 50, the two segment steerable endovascular guide system 30 and the endovascular staple applier 38 and their associated components are supplied sterile to the user.

IV. SYSTEM COMPONENTS

A. The Endovascular Graft

In representative embodiments (see Figs. 6A through 6M), the endovascular graft 12 is a single lumen endograft generally comprising two primary components: a graft 60 made of a biocompatible material, e.g., polyester, ePTFE, etc.; and optionally a most proximal stent or scaffold 70 made of a biocompatible metal or plastic material, e.g., stainless steel, nickel-titanium (Nitinol), etc. One or more stents or scaffolds 62 may

also be included in the graft mid-body for additional support (supported graft). Supported grafts (with one or more stents 62) and unsupported grafts are possible. In addition, a distal stent 63 may or may not be included.

In a representative embodiment, the preferred length of the endovascular graft 12 is between 5 cm and 30 cm and most preferably between 10 cm and 25 cm. Although, it is to be appreciated that other lengths, such as 15 and 20 cm for example, are possible to accommodate different anatomic conditions and vessel abnormalities. Desirably, a range of dimensions for the diameter of the graft 12 are provided to accommodate different anatomic dimensions of patients.

The endovascular graft 12 may include a most proximal stent 70, e.g., with diamond or "V" shaped cells, which may be sewn to the inside or outside of the proximal portion 65 of the graft e.g., with braided or monofilament suture. The most proximal stent 70 is sized and configured to accommodate secure apposition to the vessel wall, for example, at the level of the aortic arch just below, or just beyond the left subclavian artery. At this tortuous location, the graft 12 and/or stent 70 may resolve to a more elliptical or oval shape, due to the curvature of the proximal portion of the endovascular graft within the aortic arch, which may bend or curve 90 degrees or more. The stapling system 16 is adapted to apply an apposition force to deflect a portion or portions of the proximal portion 65, or other portions of, the graft 12 and/or the stent 70 against the vessel wall where the graft 12 does not naturally appose the vessel wall due to the curvature of the vessel wall, to conform the shape of the endovascular graft 12 to the vessel wall at the desired location to be secured. The ability to deflect a portion or portions of the endovascular graft is desirable because it allows the

shape of the graft 12, or portions thereof, to be customized to the patient's anatomy.

In the embodiment shown in Fig. 6A, the stent 70 extends beyond the fabric, with the extension ranging from about 0.0 mm to about 15 mm, although a wider range is possible. A supporting stent 62 is shown in the graft 12. In an alternative embodiment shown in Fig. 6B, the stent 70 does not extend beyond the fabric. The grafts in Figs. 6B and 6C are shown as an unsupported graft with a distal stent 63 and without a distal stent 63, respectively.

Additional embodiments of the graft 12 are possible to address a variety of anatomical configurations. Fig. 6D shows an unsupported tapered graft 12 wherein the proximal portion 65 includes a first diameter D1, and the distal portion 66 includes a second diameter D2. The first diameter may be greater than the second diameter in one embodiment and less than the second diameter in an alternative embodiment. The grafts in Figs. 6D and 6E are shown as an unsupported graft with a distal stent 63 and without a distal stent 63, respectively.

Fig. 6F shows one embodiment of a curved graft 12 configuration. The curved graft may be used to aid in conformance with placement in the aortic arch or other tortuous locations. As a non-limiting example, the curved graft 12 is shown without the use of the distal stent. The curved graft may be initially woven in a straight configuration, and then processed (i.e., heat set on a curved mandrel) to take the predetermined curved shape.

Fig. 6G shows an additional alternative embodiment of the graft 12. The graft 12 includes an opening 67 in the proximal portion 65 which could accommodate fluid communication with a branch artery such as the left subclavian artery, for example, and allow the graft 12 to land further proximally in the thoracic aorta, where

healthy tissue may be more readily available to secure the graft 12.

Fig. 6I shows another alternative embodiment of the graft 12. The branched graft 12 includes a small ancillary branch 68 protruding from the side of the graft, the branch 68 adapted to align with a vessel branch, such as the subclavian artery.

Figs. 6J to 6M show yet another alternative embodiment of a graft 12. The tubular graft 12 includes areas 72 for preferential bending/folding. These preferential bending/folding areas 72 allow the graft 12 to better conform to angled or tortuous anatomy. In addition, the preferential bending/folding areas 72 bias the folds 74 in a direction that is most advantageous for blood flow (i.e., the folds go in the direction of blood flow). The preferential bending/folding areas 72 may also eliminate or reduce the contact between individual stents 62 (i.e., metal scaffolding components) when the graft is placed in angled or tortuous anatomy.

As can be seen in Fig. 6J, the graft 12 includes sufficient unstented graft areas 72 in-between the stents 62 in order to allow the bending/folding to occur. The width of the unstented graft area 72 may vary depending on the application and/or the location of implantation (see Fig. 6K for example). Figs. 6K and 6L show the graft 12 in various curved configurations. As can be seen, the graft 12 is adapted to bend/fold (i.e., compress) at or near the inner radius of the curve, while the unstented graft area 72 at or near the outer radius of the curve is allowed to expand as needed.

The graft 12 may be preconfigured so the graft bends/folds at the unstented graft areas 72 as desired. A compressive force may be applied to successive stents 62 while radially pinching or squeezing the leading edge of one stent 62, to cause it and the unstented graft

material 72 between the two stents to fold within the other stent 62. Using this method, the graft 12 may be partially or completely compressed as shown in Fig. 6M. Time and/or temperature may then be used to process the graft 12 to bend/fold in a predetermined manner. The bends/folds in the graft 12 may be made permanent with time and/or temperature configurations. Generally, the lower the temperature the longer the time it takes to achieve a desired configuration. In a preferred embodiment, a temperature between about 10 degrees Celsius to about 250 degrees Celsius may be used, and more preferably between about 30 degrees Celsius to about 150 degrees Celsius. The graft may be processed to varying levels of conformity using a range of times from about 1 second to several days.

The graft 12 may include stents 62, shown with diamond or "V" shaped cells, which may be sewn to the inside or outside of the graft, e.g., with braided or monofilament suture.

Predetermined arrays of radiopaque markers made from biocompatible materials with high radiopacity (e.g., tantalum, platinum or gold) are desirably attached to the endovascular graft 12 to assist with visualization under fluoroscopy. The markers, like the stents, may be sewn to the graft, e.g., with braided or monofilament suture or can be attached to the stent. The arrays can vary. In the illustrated embodiments, there are four (4) proximal stent marker bands 78 and four (4) distal stent marker bands 80, although other combinations and positions are possible to aid in the placement of the graft.

Further details of representative constructions of the endovascular graft 12 can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,444, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery

and Implantation, Including a Prosthesis Assembly," which is incorporated herein by reference.

B. Endovascular Graft Implantation Components

1. The Endovascular Graft Delivery System

a. General Overview

The endovascular graft assembly 12 is preloaded into the delivery system 24 (see Fig. 8A), which is a single use component that is supplied to the user within its package 42 in a sterile condition (see Fig. 5). The delivery system 24 is sized and configured to facilitate accurate placement of the endovascular graft 12 and to allow the physician to maintain control of the endovascular graft 12 while the endovascular staples 36 are applied.

In the illustrated embodiment, the delivery system 24 comprises a delivery catheter 96 and a control handle 98 coupled to the proximal end of the delivery catheter 96. The delivery catheter 96 (see Fig. 8D) comprises a flexible inner assembly 100 and an outer graft retention jacket 102. The inner assembly 100 carries at its distal-most end a flexible radiopaque tracking nosecone 104.

When preloaded (see Fig. 8D), the endovascular graft 12 (a supported graft 12 is shown) may be attached to the inner assembly 100 in discrete locations. In this non-limiting example, the graft is attached in three locations, just proximal of the nosecone 104 (i.e., toward the handle 98), the proximal portion 65 of the graft may be secured by a releasable suture S1 to the inner assembly 100. Also just proximal of the nosecone 104, the inner assembly 100 may include a set of stabilizing arms 106 (or a releasable suture). In the illustrated embodiment, there are three stabilizing arms 106. The proximal portion 65 of the preloaded endovascular graft 12 may be attached to the three stabilizing arms by three releasable pull wires S2, each

threaded through eyelets in a respective one of the distal ends of the stabilizing arms 106 and through adjacent graft material. The distal end 66 of the preloaded endovascular graft 12 may also be attached to the inner assembly 100 by a releasable suture S3. These sutures S1, S2, and S3 and release wires 108, 110, and 112 (or other release means) secure the endovascular graft 12 to the inner assembly 100 for deployment to the targeted implantation site.

In an alternative embodiment, the graft 12 can be attached to the inner assembly 100 in multiple discrete locations without using the proximal stabilizing arms. It is also to be appreciated that the stabilizing arms are not limited to attaching only the proximal portion 65 to the inner assembly 100. Stabilizing arms may be used to attach any portion of the graft 12 to the inner assembly, including the most proximal stent 70, a distal stent 63, the proximal portion 65, the distal portion 66, or any other portion of the graft 12.

The separate release wires 108, 110, and 112 extend from the handle 98 along the inner assembly 100 (see Fig. 9). The separate release wires 108 and 112 are independently coupled to the respective suture S1 holding the most proximal stent 70 (release wire 108), and the suture S3 at the distal portion 66 of the endovascular graft 12 (release wire 112). The release wires 110 are continuations of the release wires S2 threaded through the stabilizing arms 106 (as previously described), so that, in the illustrated embodiment, there are actually three release wires 110, one for each arm 106. Controls 114, 116, and 118 on the handle 98 are coupled to the separate release wires 108, 110 (commonly coupled to the three wires), and 112, as will be described in greater detail later, to independently release the sutures or release wires at one location, without necessarily

releasing the sutures or release wires at another location. The separate and independently controllable release wires 108, 110, and 112 make possible the release of the endovascular graft 12 in a prescribed order, to deploy the endovascular graft 12 in a desired sequence during the graft deployment process, as will be described in greater detail later.

The graft retention jacket 102 is sized and configured to slide over and along the inner assembly 100 from an advanced position over the preloaded endovascular graft 12 (shown in phantom lines in Fig. 8E) to a retracted position spaced away from the preloaded endovascular graft 12 (shown in solid lines in Fig. 8E). Fig. 8E shows an embodiment of an unsupported graft, and Fig. 8F shows an embodiment of a supported graft. One or more radiopaque marker(s) 120 is positioned at or near the leading edge of the graft retention jacket 102 to assist in visualization under fluoroscopy.

As can be seen in Figs. 8B and 8C, a jacket control mechanism 122 coupled to controls 124 and 126 on the handle 98 affects retraction of the graft retention jacket 102 in a stepwise fashion -- using first control 124 and then control 126, as will be described later -- as well as the re-advancement of the retention jacket 102 using the single control 126 after the graft 12 has been fully deployed and it is time to withdraw the delivery system.

When in its advanced position, the graft retention jacket 102 protects the preloaded endovascular graft 12 as it is advanced through the patient's vasculature. When in its retracted position, the graft retention jacket 102 frees the preloaded endovascular graft 12 for deployment by operation of the controls 124 and 126 on the handle 98 during the graft deployment process.

The actuating means on the control handle 98 (see

Figs. 8B and 8C) may include a jacket retraction knob 124 and a jacket retraction slide 126, which are coupled to the jacket control mechanism 122 just described. The jacket retraction knob 124 is actuated by rotation and is coupled to gear components of the jacket control mechanism 122 within the handle 98. The gear components apply a mechanical advantage in response to rotation of the knob 124 sufficient to overcome the resistance of the graft retention jacket 102 to axial movement beyond the proximal portion of the graft and optionally the mid-body stent(s) 62, when included, of the endovascular graft 12. Once passed the proximal portion of the graft, the gear components of the jacket control mechanism 122 may be automatically released from the jacket retraction knob 124 (the knob 124 will accordingly spin freely), and subsequent control passes to the jacket retention slide 126. Pulling on the jacket retention slide 126 (which may not provide a mechanical advantage) suffices to complete the retraction of the jacket 102. This control sequence provides the physician with tactile feedback during the retraction of the jacket 102. After retracted in this manner, the jacket 102 can be advanced back toward the nosecone 104 using the jacket slide 126 when it is time to withdraw the delivery system after release of the graft 12.

In an alternative embodiment of the jacket control mechanism 122 within the handle 98, the delivery system 24 may have the ability to produce a mechanical advantage for the full length of the retraction of the graft retention jacket 102. The mechanical advantage produced may be disengaged by the physician at any point during the retraction of the jacket 102, and the mechanical advantage may be reengaged if desired, at any point during the retraction of the jacket 102. The mechanical advantage may be produced using the gear system as

described, or may be produced by other means such as a reel and cable system, or an exterior threaded rod with an internal threaded component for example.

As previously described, the actuating components on the control handle may include the proximal release slide 114, the graft release slide 116, and the distal release slide 118. The proximal release slide 114 is coupled to the release wire 110 for the proximal portion 65 of the graft. The graft release slide 116 is coupled to the three separate release wires 110 for the stabilizing arms 106. The distal end release slide 118 is coupled to the separate release wire 112 for the distal portion 66 of the endovascular graft 12.

Once the graft retention jacket 102 is retracted (as just described), pulling on the proximal release slide 114 opens the proximal portion 65 of the graft. Pulling on the distal end release slide 118 opens the distal portion 66 of the endovascular graft 12. Despite opening the proximal portion 65 and the distal portion 66, the proximal portion 65 of the endovascular graft 12 remains attached to the inner assembly 100 of the endovascular graft delivery system. The physician maintains control of the endovascular graft 12 for further final positioning and for the application of the staples 36, as will be described in greater detail later.

Once positioned in a desired location and/or after insertion or implantation of staples to secure the endovascular graft 12 to the vessel wall, pulling on the graft release slide 116 releases the endovascular graft 12 from the stabilizing arms 106 and the delivery catheter 96.

An alternative embodiment of the delivery catheter 96 is shown in Fig. 8G without stabilizing arms. In this embodiment, the endovascular graft 12 (an unsupported graft 12 is shown) may be attached to the inner assembly

100 at discrete locations. In this non-limiting example the graft is attached in two locations, just proximal of the nosecone 104, (i.e., toward the handle 98), with the proximal portion 65 of the endovascular graft 12 being secured by a releasable suture S1 to the inner assembly 100, and the distal end of the preloaded endovascular graft 12 may also be attached to the inner assembly 100 by a releasable suture S3. These sutures S1 and S3 secure the endovascular graft 12 to the inner assembly 100 for deployment to the targeted implantation site, as previously described. It is to be appreciated, as previously described, that the graft 12 can be attached to the inner assembly 100 in multiple discrete locations, and without using the proximal stabilizing arms, to maintain control of the graft 12. The use of release wires, for example, as described above may be used to attach the graft 12 to the inner assembly 100 to maintain control of the graft 12 while implantation of staples takes place.

If desired, and as shown in phantom lines in Fig. 8A, a stationary outer jacket 220 may be provided that extends for a distance from the proximal end of the handle 98 over the delivery catheter 96 (the jacket 102), which slides within the stationary outer jacket 220. The stationary jacket 220 provides a seal interface with a hemostatic valve of the introducer sheath at the access site. The stationary jacket 220 can be made of a suitable medical grade plastic, such as Fluroinated Ethylene Propylene (FEP) as a non-limiting example. The stationary outer jacket 220 provides column strength and lubricity to reduce friction during sliding actuation of the jacket 102.

In a representative embodiment, the handle 98 (e.g., near the sliding controls 114, 116, and 118 just described) includes a hemostatic seal assembly 128. As

Fig. 9 shows, a flush passage 130 (for conveying heparinized saline to flush the delivery catheter 96 prior to deployment) communicates with the space between the inner assembly 100 and jacket 102 through the hemostatic seal assembly 128. As Fig. 9 also shows, the individual release wires 108, 110, and 112 for the proximal portion release slide 114, the graft release slide 116 (one release wire 110 for each stabilizing arm 106), and the distal end release slide 118, as previously described, also pass from the slide controls 114, 116, and 118 within the handle in a sealed fashion through the hemostatic seal assembly 128 for passage along the inner assembly 100 to the distal end of the delivery catheter 96, where they connect to their respective components, as previously described. The hemostatic seal assembly 128 allows flushing to occur and prevents blood, which can enter the space between the outer jacket 102 and the inner assembly 100 catheter tube during use, from entering the interior of the handle 98.

The delivery catheter 96 is desirably sized to present a minimum diameter according to the diameter of the endovascular graft 12 it carries. The delivery catheter 96 is desirably sized and configured with a lumen accommodating conventional over-the-wire delivery within a patient's vasculature, e.g., using a conventional 0.035 or 0.038 inch guide wire. In a representative embodiment, the overall length of the delivery catheter 96 (not including the handle 98) is preferably between 40 and 120 cm and most preferably between 60 and 110 cm.

Further details of representative constructions of a delivery system 24 can be found in co-pending, commonly owned United States Patent Application Serial No. 11/255,116, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery

and Implantation," which is incorporated herein by reference.

2. Endovascular Stapling System

The endovascular stapling system 16 comprises a steerable endovascular guide system 30 comprising a first steerable guide 30A and a second steerable guide 30B, and a companion obturator 32 (see Figs. 10A and 10B). The endovascular stapling system 16 also comprises a plurality of endovascular staples 36 (Fig. 11A) and, desirably, a cassette 34 for holding the staples 36 (see Fig. 11B), as well as an endovascular staple applier 38 (see Figs. 12A and 12B). It is to be appreciated that the steerable endovascular guide system 30 may comprise a single guide device incorporating the features of the first steerable guide 30A and the second steerable guide 30B (see Fig. 10D).

The stapling system 16 may be used to apply an apposition force to the endovascular graft 12 to modify the shape of the endovascular graft to conform to the shape of the vessel wall. The endovascular stapling system 16 is also adapted to provide apposition force for improved sealing and fixation to eliminate movement and/or migration of the endovascular graft 12 within the vascular system. The endovascular stapling system 30 and endovascular staples 36 may also be used without the use of a graft 12 to close the entrance of a vessel dissection to blood flow.

a. Steerable Endovascular Guide and Companion Obturator

Referring to Figs. 10A through 10D, the steerable endovascular guide system 30 is a single use system that is supplied with a companion obturator 32 to the user within its package 50 in a sterile condition. The steerable endovascular guide system 30 is sized and configured to direct the endovascular staple applier 38

through at least one or more resolved angles to the desired location in a vessel for implantation of one or more endovascular staples 36, i.e., through one or more steerable segments 167A and 167B. In one embodiment shown in Figs. 10A and 10B, steerable segment 167A is a component of the first steerable guide 30A, and steerable segment 167B is a component of the second steerable guide 30B.

In an additional embodiment shown in Fig. 10D, steerable segment 167A and steerable segment 167B are both components of an integrated endovascular guide system 30.

The first (inner) steerable endovascular guide 30A includes a guide tube 164A, and a handle 166A coupled to the proximal end of the guide tube 164A. The guide tube 164A defines an open interior lumen 168A accommodating passage of the endovascular staple applier 38 (during use).

The second (outer) steerable endovascular guide 30B is similar to the first steerable guide 30A, except the second steerable guide tube 164B has a shorter overall length, as will be described below. The second steerable guide 30B includes a guide tube 164B, and a handle 166B coupled to the proximal end of the guide tube 164B. The guide tube 164B defines an open interior lumen 168B accommodating passage of the obturator 32 (during deployment) and the guide tube 164A of the first steerable endovascular guide segment 30A (during use).

The distal portion of the two segment steerable endovascular guide system 30 can be deflected in one or more distinct segments comprising the first steerable segment 167A and the second steerable segment 167B (as shown in phantom lines in Figs. 10A and 10B), and re-straightened by deflection means, such as steering wires or pull cords (not shown) coupled to a first rotational

deflector knob 170A on the handle 166A of the first steerable guide 30A for control of the first segment 167A, and a second deflector knob 170B on the handle 166B of the second steerable guide 30B for control of the second segment 167B. Each deflector knob 170A, 170B is adapted to move its respective steerable segment 167A, 167B, from a first, generally straight position for deployment to the general targeted region, to a second, articulated position for alignment of the distal end of the guide tube 164A, and the staple applier 38, to be in contact with the vessel wall for staple deployment.

In the two component configuration, the guide tube 164A of the first steerable endovascular guide 30A is inserted (i.e., nested) into the lumen 168B of the guide tube 164B of the second steerable guide 30B until the distal end of the handle 166A is positioned near or against the proximal end of the handle 166B. The length of the second guide tube 164B is less than the length of the first guide tube 164A (see Fig. 10B). This allows the distal end segment 167A to be independently articulated (via the rotational deflector knob 170A) as it may not be confined within the second guide tube 164B. In addition, the first steerable guide 30A may be selectively moved longitudinally relative to the second steerable guide 30B. Longitudinal adjustment of the first steerable guide 30A allows the length of the distal end segment 176A to be adjusted. Because the first guide tube 164A passes through and extends beyond the distal end of the second guide tube 164B, when the distal end segment 167B of the second guide tube 164B is articulated (via the rotational deflector knob 170B), the first guide tube 164A articulates with the second guide tube 164B. The nested guide tubes 164A and 164B allow for distal end segments 167A and 167B to be independently steerable and longitudinally adjustable to produce at least one

resolved angle to aid in positioning the stapler applier 38 in a desired location to produce a force resolution desired to deploy a staple 36.

In a representative embodiment, the over-all length of guide tube 164A, not including handle 166A, is preferably between 40 and 120 cm and most preferably between 60 and 110 cm, and the length of the two segment deflectable tip is preferably between 1.0 and 10 cm and most preferably between 2 and 5 cm. The first segment 167A is preferably between about 1.0 and 5.0 cm, and the second segment 167B is preferably between about 1.0 and 2.5 cm. It is to be appreciated that the lengths of the segments may change depending on the body lumen in which the endovascular guide system is being used. C-shaped radiopaque markers 172A and 172B may be located at or near the distal tip of the guide tube 164A and 164B respectively, to aid in orientation under fluoroscopy.

In yet an additional embodiment of a steerable endovascular guide shown in Fig. 10E, the steerable guide 30C may include a single control handle 166C with a single steerable guide tube 164C, as compared to the steerable guides shown in Fig. 10B and 10D, where assemblies are combined to produce a steerable endovascular guide. The control handle 166C may be adapted for steering the guide tube 164C in multiple directions using, for example, a first deflector knob 170C and second deflector knob 170D. As can be seen, the single guide tube is shown with two steerable segments 167C and 167D.

In a representative embodiment, the obturator 32 is desirably sized and configured with a lumen 174 accommodating conventional over-the-wire delivery within a patient's vasculature, e.g., using an appropriately sized guide wire.

Further details of representative constructions of a

steerable endovascular guide 30A can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,619, filed October 20, 2005, and entitled " Devices, Systems, and Methods for Guiding an Operative Tool into an Interior Body," and co-pending, commonly owned United States Patent Application Serial No. 11/255,116, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which are both incorporated herein by reference.

b. The Endovascular Staple and Companion Cassette

The endovascular staple 36 (see Fig. 11A) is a single use component that is supplied, desirably in a companion cassette 34, to the user within a package in a sterile condition. The endovascular staple 36 is sized and configured to attach the endovascular graft 12 to a vessel wall, and/or to close the entrance of a vessel dissection.

In the illustrated embodiment (see Fig. 11A) the endovascular staple 36 comprises a main staple body 176 that is helical-shaped. The helical-shape allows the endovascular staple 36 to pierce and engage tissue in response to rotation of the main staple body 176, thereby securing attachment of the endovascular graft 12 to a vessel wall.

In a representative embodiment, the main staple body 176 is manufactured from medical grade wire having a diameter between about 0.1 mm and 1.0 mm. In a representative embodiment, the endovascular staple 36 is approximately between about 2 mm and 12 mm in over-all length and approximately between about 1.0 mm and 10 mm in maximum diameter. The leading end 178 of the main staple body 176 is desirably sharpened to facilitate atraumatic deployment through the graft materials and

vessel wall. The proximal end 180 of the main staple body 176 is desirably closed to prevent over-penetration of the endovascular staple 36.

Desirably, a plurality of staples 36 (e.g., ten) are provided in a convenient cassette 34 (see Fig. 11B), to allow easy and accurate loading into the endovascular staple applier 38. The cassette 34 includes a base 208 having a plurality of foil covered spaced apart staple ports or stations 210, each sized to house a staple 36. A deformable cover 212 (e.g. a foil cover) may be positioned over each staple port 210, and may include a precut shape, such as an "X". The precut "X" allows access for the staple applier 38 to the staple 36 within the port 210, and when the staple applier is inserted the deformable cover 212 and associate "X" deform 213, providing a visual indication to the user which port has been accessed. In use, an operator identifies a port 210 having a precut "X" in the cover 212. The operator operates the staple applier 38 to load the staple 36 from the foil covered port 210, as will be described in greater detail below. After implanting the withdrawn staple 36, the operator again identifies a port 210 having a precut "X" in the cover 212. The operator again operates the staple applier 38 to load the staple 36 from the foil covered port 210 for implantation. In this way, the cassette 34 aids the operator in loading individual staples on the staple applier 36 for implantation in a single fire (one at a time) fashion.

Further details of representative constructions of an endovascular staple 36 and companion cassette 34 can be found in co-pending, commonly owned United States Patent Application Serial No. 11/255,116, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which is incorporated herein by reference.

c. Endovascular Staple Applier

(1) Overview

The endovascular staple applier 38 (see Figs. 12A and 12B) is a single use component that is supplied to the user within a package 48 in a sterile condition. In the illustrated embodiment, the endovascular staple applier 38, a supply of endovascular staples 36, and the staple cassette 34 are provided, for the sake of convenience, in a single package 48. The endovascular staple applier 38 is sized and configured to pass through the lumen 168A of the first steerable endovascular guide 30A guide tube 164A, which may be nested within the lumen 168B of the second steerable endovascular guide 30B guide tube 164B and to be selectively operated to implant one or more endovascular staples 36 through the graft (when used) and into the vessel wall.

In the illustrated embodiment, the endovascular staple applier 38 comprises an applier catheter 182 and a control handle 184 coupled to the proximal end of the applier catheter 182. The applier catheter 182 carries a rotationally driven member 186 at its distal end. A battery powered motor 188 enclosed within the handle 184 is coupled to the driven member 186, to selectively rotate the driven member 186 either in a forward (e.g., clockwise) direction and reverse (e.g., counterclockwise) direction. A control circuit 190 in the handle 184 is coupled to the motor 188 and to a forward control button 192 and a reverse control button 194 on the handle. The control circuit 190 governs operation of the motor 188 according to pre-programmed operating parameters in response to user commands received by manipulation of the buttons 192 and 194.

In use, an endovascular staple 36 is loaded into the driven member 186 from the cassette 34, e.g., by placing the distal end of the applier catheter 182 into an

exposed staple port 210 in the cassette 34 and pressing the reverse control button 194 (see Fig. 12C). The now loaded endovascular staple applier catheter 182 is passed through the nested guide tubes 164A and 164B of the endovascular guide system 30, which has been manipulated beforehand to be at an intended implantation site for the endovascular staple 36 (see Figs. 13A to 13C). To simplify Figs. 13A to 13C, the delivery system 24 is not shown.

As can be seen in Fig. 13A, the nested guide tubes 164A and 164B are adapted to guide the staple applier catheter 182 through one or more steerable segments 167A and 167B to the desired location in a vessel for implantation of one or more endovascular staples 36. The steerable guide system 30 may be used to apply the desired resolution of force to the endovascular graft 12 to modify the shape or form of the endovascular graft to conform to the shape of the vessel wall. This resolution of force can be utilized to deflect a portion or portions of the endovascular graft against the vessel wall to implant a staple 36.

Once the endovascular staple applier catheter 182, loaded with a staple 36, is positioned at the desired location and the resolution of force is achieved, the physician presses the forward control button 192 to command rotation of the endovascular staple 36 in the forward direction, i.e., into tissue (see Fig. 13B).

The control circuit 190 is desirably pre-programmed to require a two-stage implantation process. The first stage commands only a partial implantation of the staple 36. In the first stage, the physician is allowed to ascertain whether the staple 36 is placed correctly at the desired location and that the desired located is suitable for implantation of the staple 36. While in the first stage, the physician is allowed to retract the

staple 36 (by pressing the reverse control button 194) and to re-position the staple 36.

The control circuit 190 commands a full final deployment of the staple 36 only after a deliberate entry of the second stage. In the first and second stages, the control circuit 190 generates audible tones and/or visual indicators (e.g., blinking lights) during operation of the motor 188, to indicate the position of the staple and available direction of motion.

Once the staple 36 is implanted, the endovascular staple applier 38 is withdrawn through the nested guide tubes 164A and 164B. The physician identifies another port 210 having a precut "X" in the cover 212. The staple applier 38 is reloaded. The two segment endovascular guide system 30 is manipulated to another desired implantation site, and the endovascular staple applier 38 (reloaded with another staple 36) is redeployed and operated in the manner just described (see Fig. 12C). The endovascular staple applier 38 is intended to be loaded, deployed, and reloaded in this way multiple times for a single patient.

Further details of representative constructions of an endovascular staple applier 38 and methods of its use can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,950, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including the Use of a Fastening Tool" which is incorporated herein by reference.

(2) Tracking the Relative Position of the Endovascular Staple Applier in the Endovascular Guide

As seen in Fig. 14A, the endovascular staple applier 38 desirably includes indicia 196, which is visible to a naked eye (i.e., without resort to fluoroscopic

visualization or other visualization techniques that augment human vision) that indicates the extent to which the driven distal end 186 of the applier catheter 182, which carries the endovascular staple 36, resides within the guide tube 164A of the first steerable endovascular guide 30A. In particular, the visible indicia 196 indicates when the driven distal end 186 of the applier catheter 182 and the staple 36 it carries have arrived at a predetermined location within the guide tube 164A near to the distal end of the guide tube 164A. In this way (see Figs. 14B and 14C), the physician can quickly and accurately ascertain, without resort to fluoroscopic visualization, that the distal end 186 of the applier catheter 182, and the endovascular staple 36 it carries, are positioned adjacent the end of the guide tube 164A, ready for final deployment, once the guide tube 164A is placed at the intended implantation site. The visible indicia 196 can also indicate the extent to which the driven distal end 186 of the applier catheter 182 has been extended outside the distal end of the guide tube 164A.

In the illustrated embodiment (see Fig. 14A), the indicia 196 comprises visible material or markings M on the most proximal section of the applier catheter 182, adjacent the handle 184, that is marked or colored differently or is otherwise differentiated from the remainder of the applier catheter 182. In a representative example, a prescribed length of contrast-colored tubing 198 can be placed at the most proximal end of the applier catheter 182, where it exits the handle 184.

The contrast-color tubing 198 has a prescribed length. The distal end of the tubing 198 marks a line of differentiation between the tubing 198 and the remainder of the applier catheter 182. The length is selected so

that the distal end of the tubing 198 registers with the insertion port/hemostatic seal 200 on the handle 166A of the first steerable endovascular guide 30A (see Fig. 14B) when the driven distal end 186 of applier catheter 182 rests at a desired inset distance d within the distal end of the guide tube 164A (see Fig. 14C).

In this way, the indicia 196 indicates when the applier catheter 182 has reached a desired location relative to the end of the guide tube 164A, and is ready to be further advanced to implant the endovascular staple 36. The contrast-color tubing 198 may further include additional markings M along its length by which the physician can gauge advancement of the applier catheter 182 beyond the guide tube 164A.

The indicia 196 makes it possible for the physician, without resort to fluoroscopic visualization, to always know the position of the endovascular staple 36 and staple applier 182 relative to the end of the endovascular guide system 30 (e.g., within or outside the guide tube 164A.

(3) The Motor Control Circuit

In a representative embodiment (see Figs. 15A and 15B), the control circuit 190 for the motor includes an optical encoder 250 coupled to a counting function 252, to enable counting the revolutions of the battery powered motor 188. The control circuit 190 also includes a sensing function 254 that senses the magnitude of current being drawn by the motor 188, for deriving torque that the motor 188 is encountering. The control circuit 190 also includes a comparison function 256 that compares the magnitude of the sensed torque (current) with set torque limits in either the forward or reverse direction, to change the state of operation should excess torque conditions be encountered.

The control circuit 190 carries embedded code, which

expresses pre-programmed rules or algorithms under which different operation states are entered and motor command signals are generated in response to input from the external control sources and the counting, sensing, and comparison functions. The pre-programmed rules or algorithms of the control circuit 190 are designed to conserve power consumption, placing the circuit into a standby (wait) mode between staple loading and deployment cycles. This makes it possible to power up the staple applier just once and to leave the staple applier on during an entire procedure, avoiding time consumed in repeated power ups and power downs. The pre-programmed rules or algorithms of the control circuit also dictate that a desired sequence of steps is faithfully followed in loading, deploying, and reloading the staples, prompting the physician at the initiation of each step and not allowing any short-cuts or deviations along the way.

Further details of representative constructions of an endovascular staple applier 38 and methods of its use, including features of the pre-programmed rules or algorithms of a representative control circuit 190, can be found in co-pending, commonly owned United States Patent Application Serial No. 11/254,950, filed October 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including the Use of a Fastening Tool" and co-pending, commonly owned United States Patent Application Serial No. 11/488,305, filed July 18, 2006, and entitled "Endovascular Aneurysm Devices, Systems, and Methods", which are both incorporated herein by reference.

D. The Instructions for Use, Including Deploying an Endovascular Graft

The instructions for use 58 can direct use of catheter-based technology via a peripheral intravascular

access site, such as in the femoral artery, optionally with the assistance of image guidance. Image guidance includes but is not limited to fluoroscopy, ultrasound, magnetic resonance, computed tomography, or combinations thereof. The instructions for use may include instructions for implanting an endovascular graft 12 to repair an aortic aneurysm, for example. The instructions for use may also include instructions for implanting endovascular staples 36 without the use of a graft 12, for the repair of an aortic dissection, for example, as will be described below.

Figs. 16A through 18B show representative embodiments of the steps that representative instructions for use 58 can incorporate or direct.

In a representative embodiment, the instructions for use 58 may include the achievement of percutaneous vascular access by conventional methods into the femoral artery, for example. In this arrangement, the patient is placed on an imaging table, allowing fluoroscopic visualization from the aortic arch to the femoral artery bifurcations. Access is secured to one or both contralateral and ipsilateral branches by standard techniques using introducer sheaths (which can be supplied as part of the kit 40). Using fluoroscopic guidance, access to the patient's aortic arch can be achieved with an appropriately sized guide wire through one or both femoral access sites.

1. Position the Endovascular Graft in the Targeted Endovascular Treatment Site

In this arrangement, the instructions 58 for use may include positioning of the endovascular graft 12 to be deployed. An unsupported graft, and a delivery system 24 including stabilizing arms 106 are shown. It is to be appreciated that other configurations of grafts 12, and delivery systems 24, i.e., without stabilization arms,

both as previously described, may be used and are intended to be included in the scope of the invention. It is also to be appreciated that at anytime during or after the retraction of the graft retention jacket, the entire graft assembly may be repositioned within the vasculature. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include, but are not limited to:

(i) after flushing the delivery system 24 with heparinized saline, positioning the delivery system 24 within an aortic abnormality over the guide wire via a femoral access site, which has been previously established in conventional fashion (Fig. 16A);

(ii) visualizing the proper position and orientation of the endovascular graft 12 using the radiopaque markers (e.g., proximal stent markers 78, distal stent markers 80 and the marker(s) 120 positioned at or near the leading edge of the graft retention jacket 102;)

(iii) withdrawing the graft retention jacket 102 of the delivery system 24 by rotating the jacket retraction knob 124 and/or sliding the jacket retraction slide 126 away from the patient. Alternatively, the mechanical advantage mechanism may be terminated by the physician at any point during the jacket retraction. The instructions may note that the proximal portion 65 of the endovascular graft 12 will not open during retraction of the jacket 102 and that the proximal portion 65 and distal portion 66 of the graft remain collapsed and connected to the delivery system 24, and that at anytime during or after the retraction of the jacket retention jacket the entire graft assembly may be repositioned within the vasculature (Fig 16B);

(iv) verifying the position and orientation of the endovascular graft 12 using the radiopaque markers (e.g.,

78, 80, and 120,); and opening the distal portion 66 by retracting the distal release slide 118. Alternatively, the distal portion 66 may open on its own, without the need to operate any controls.

(v) releasing the endovascular graft proximal portion 65 from the delivery system by retracting the proximal end release slide 114 on the handle away from the patient (Fig. 16C). When a delivery system 24 incorporating stabilizing arms 106 or other release wires are used, the instructions may note that the proximal portion (or other portions) of the endovascular graft 12 may still remain secured to the delivery system 24. The physician thereby maintains control and can manipulate the position and orientation of the graft assembly 12 during deployment of endovascular staples.

The instructions may also note that the use of release wires in place of stabilizing arms 106 may be used to attach the endovascular graft 12 to the inner assembly 100 to maintain control of the graft 12 while implantation of endovascular staples takes place.

With an alternative embodiment of a delivery system 24 without stabilizing arms, as previously described, after the proximal portion 65 and distal portion 66 are released from the delivery system, the graft 12 is free of the delivery system 24 and remains in position with the radial force of the proximal stent 70 and/or additional stents incorporated with the graft 12. It is to be appreciated that any of the delivery systems described herein may be removed at this stage of the procedure, or may be removed after endovascular staples have been deployed, as described below.

2. Deploy Endovascular Staples to Secure the Position of the Endovascular Graft

The instructions for use 58 may next instruct securing of the position of the proximal portion of the

endovascular graft 12 using endovascular staples 36. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include, but are not limited to:

(i) placing an appropriate length and sized guide wire via the femoral access site into the aortic arch. The endovascular graft 12 includes distal end radiopaque markers 80 that outline the opening of the distal portion 66 of the endovascular graft 12. The guide wire is to be placed through this opening and its position verified using standard endovascular techniques;

(ii) using fluoroscopic guidance, advancing the second steerable endovascular guide 30B with the obturator 32 over the guide wire into a position within the proximal neck of the thoracic aneurism (Fig. 16D). The C-shaped radiopaque marker 172B located at the distal tip of the guide tube 164B will aid in fluoroscopic visualization. Position the steerable endovascular guide system 30 at the desired location for endovascular staple implantation within a desired location on the endovascular graft 12, (e.g., between the marker bands 78 on the proximal stent 70 and the bottom edge of the proximal stent 70.) In addition, the steerable endovascular guide system 30 may be used to contact and apply an apposition force to deflect a portion or portions of the proximal portion, or other portions of, the graft 12 and/or the stent 70 against the vessel wall to conform the shape of the endovascular graft 12 to the vessel wall at the desired location;

(iii) removing the guide wire and obturator 32 to open the lumen 168B of the second steerable endovascular guide 30B and inserting the guide tube 164A of the first steerable endovascular guide 30A into the lumen 168B. (Alternatively, the first steerable endovascular guide 30A and the second steerable endovascular guide 30B may

be inserted at the same time with only one obturator in the lumen 168B of the second steerable endovascular guide 30B.)

(iv) deflecting the distal segments 167A and/or 167B of the two segment steerable endovascular guide system 30 toward the first intended staple implantation area by rotating the first and/or second deflector knobs 170A, 170B to achieve one or more bends or angles, while observing with fluoroscopic guidance. The instructions may note that the C-shaped fluoroscopic markers 172A and 172B will appear as a straight line when their respective catheters are oriented laterally, as a right curve "(" when oriented anteriorly, and as a left curve ")" when oriented posteriorly. Alternatively, the manipulation of the guide system (deflecting the distal segments) can be performed after the insertion of the endovascular staple applier;

(v) turning on the endovascular staple applier 38 by pressing one or more of the control buttons 194, 192 for a predetermined amount of time. This can initiate a self-checking sequence with audible and/or visual indicators. At the end of this sequence, the reverse indicator 202 will indicate that the endovascular staple applier 38 is ready to load the first endovascular staple 36. The instructions may note that, if at the end of the self check sequence, the error light 204 is illuminated, the endovascular staple applier 38 has encountered an error. The error can be cleared by pressing one or more of the control buttons 194,192 for a predetermined amount of time. After the error has been cleared, the self check sequence will initiate. If the error light 202 can not be cleared the endovascular staple applier 38 is not functional and should not be used;

(vi) load the staple by pressing the reverse command button 194 on the handle. While the motor 188 is running,

insert the distal end of the endovascular staple applier catheter 182 into a port 210 having a precut "X" in the cover 212 of the cassette 34. The reverse indicator 202 will illuminate, and the endovascular staple will be drawn from the cassette into the distal end of the staple applier 38. When the endovascular staple 36 is loaded, an audible tone (e.g., two short beeps) will be heard, and the forward indicator 206 will illuminate. This indicates that the endovascular staple 36 is now preloaded in the staple applier 38, and the applier 38 can be removed from the cassette 34. The precut "X" in the cover 212 deforms with the insertion of the staple applier 38. The instructions may urge the physician to verify that the endovascular staple 36 is in place by visually inspecting the distal tip of the applier 38;

(vii) while stabilizing the control handle 160C or handles 166A and 166B of the endovascular guide system 30 relative to the patient, inserting the now-loaded endovascular staple applier 38 through the hemostatic seal at the proximal end of the first steerable endovascular guide control handle 166A. The instructions may direct the physician to observe the location of the visible contrast-color tubing 198 or other indicia on the proximal end of the applier catheter 182 and to halt further insertion of the staple applier 38 when the end of the contrast-color tubing 198 registers with the insertion port/hemostatic seal on the handle of the steerable endovascular guide (as shown in Fig. 14B). This indicates that the distal end of applier catheter 182 rests a desired distance from the distal end of the guide tube 164 (as shown in Fig. 14C);

(viii) under fluoroscopic guidance, advancing the endovascular staple applier 38 through the steerable endovascular guide system 30 until the endovascular staple applier 38 emerges from the distal end of the

endovascular guide system 30 and contacts the endovascular graft 12. Continue to advance the endovascular staple applier 38 until resistance is felt and/or visual indication of apposition can be seen using fluoroscopy. This indicates that the endovascular staple applier 38 is in apposition against the endovascular graft 12 and against the vessel wall at the desired location for staple deployment, and that the nested first and second steerable endovascular guide tubes 164A and 164B are fully or partially resolving the generally opposite apposition force. This resolution of force can be applied with either the staple applier 38 or endovascular guide system 30 alone, or in combination to deflect a portion or portions of the proximal portion, or other portions of the graft 12 and/or stent 70 against the vessel wall to conform the shape of the endovascular graft 12 to the vessel wall at the desired location.

(ix) using the control handle 184 of the endovascular staple applier 38, pressing the forward control button 192 for achieving the first stage of endovascular staple deployment. The endovascular staple will partially deploy and pause. An audible tone may be heard (e.g., four beeps) and the forward and reverse indicator 202 and 206 will illuminate (e.g., alternatively blink), indicating that the operator may continue deployment or withdraw the endovascular staple 36 back into the applier 38. The instructions may note that, in the event of a power loss when the staple 36 is partially deployed, the staple may be removed manually, for example, by manually rotating the handle 184 and catheter 182 in a counter-clockwise direction until the staple 36 disengages from the graft and tissue. The staple applier 38 can be removed from the endovascular guide 30 in this condition;

(x) if the endovascular staple 36 is not in the

desired location, pressing the reverse control button 194 re-houses the staple 36 inside the staple applier 38 for re-positioning;

(xi) if the endovascular staple 36 is in the desired position, completing the final stage of staple deployment by pressing the forward control button 192 to implant the endovascular staple 36 through the graft materials and into the vessel wall (Fig. 16E). When complete, an audible tone (e.g., three beeps) is heard and the reverse indicator 202 will illuminate; Fig. 16F shows an alternative configuration of the final stage of staple deployment, similar to Fig. 16E, except that an alternative deployment system 24 without stabilizing arms has been previously removed prior to the deployment of endovascular staples 36.

(xii) remove the endovascular staple applier 38, leaving the steerable endovascular guide system 30 in place;

(xiii) as needed, the steerable endovascular guide and/or the staple applier can be flushed with heparinized saline to prevent clotting in the lumens;

(xiv) identifying a port 210 having a precut "X" in the cover 212 to locate the next available endovascular staple port. Load the next endovascular staple in the manner described above;

(xv) repositioning the steerable endovascular guide system 30 to the next desired implantation site for an endovascular staple 36. Desirably, the physician straightens the first segment 167A and second segment 167B of the steerable endovascular guide system 30 between rotating in within the endovascular graft 12, to prevent accidental dislodgment or movement of the graft assembly 12;

(xvi) deploying the next endovascular staple 36 through the steerable endovascular guide 30 in the manner

described above. Typically, 4 to 6 endovascular staples, evenly distributed about the circumference of the endovascular graft 12, will serve to secure the position of the graft 12 within the vessel (see Fig. 16G). Fig. 16H shows an alternative placement of the endovascular graft 12. As can be seen, the endovascular graft 12 incorporates an open graft portion 67 and is positioned more proximal within the aortic arch, proximal to the left subclavian artery. This position - proximal to the left subclavian artery - may be necessary in anatomies where the diseased tissue is so extensive that there is insufficient healthy tissue distal to the left subclavian artery to provide a sufficient landing zone for one or more staples 36. In prior systems where there was insufficient healthy tissue distal to the left subclavian artery necessary to provide a sufficient landing zone for barbs or hooks, the left subclavian artery was sacrificed, and then grafted to the left common carotid artery. The present systems and methods overcome this problem with the use of the open graft section 12 that maintains a fluid flow communication path to the left subclavian artery, and the ability to secure and seal the endovascular graft 12 in this tortuous location.

(xii) after deployment of the last endovascular staple, removing the endovascular stapler applier 38 from the steerable endovascular guide system 30;

(xiii) removing the steerable endovascular guide system 30 by first re-advancing the obturator 32 and guide wire (if appropriate) into the steerable endovascular guide system 30.

3. Complete the Endovascular Graft Deployment

The instructions for use 58 may next include the completion of the deployment of the endovascular graft 12, which may (or may not) remain in a secured but

partially deployed condition during the deployment of the endovascular staples, as above described. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include, but are not limited to:

(i) moving to the femoral access site, where the delivery system 24 resides;

(ii) releasing the stabilizing arms 106 or other release wires from the graft by retracting the graft release slide 116 on the handle of the delivery system away from the patient. The endovascular graft 12 is now fully released (Fig. 16J);

(iii) rejacketing the delivery system 24 by holding the jacket retention slide 126 and slowly retract the delivery system 24, until the nosecone seals into the proximal end of the jacket 102;

(iv) remove the delivery system 24 from the patient, leaving the guide wire and femoral access introducer sheath in place if appropriate.

4. Completion of the Procedure

The instructions for use 58 may next include the completion of the procedure. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include, but are not limited to:

(i) performing post-implant aortic angiography to evaluate the implantation;

(ii) checking for endovascular leaks around the endovascular graft 12. If a leak is observed, standard endovascular techniques can be used to resolve. Additional staples may be placed, in the manner described above;

(iii) checking for proper location, blood flow, and patency of the endovascular graft 12;

(iv) removing the guide wires and femoral access

sheaths and close the femoral arteriotomies according to standard practice to complete the procedure. (Fig. 16K).

It is to be appreciated that the general steps just described do not necessarily need to follow the order in which they were described. It is also to be appreciated that fasteners may be applied to the distal region 66 of the endovascular graft 12 as well (as can be seen in Fig. 16K).

E. The Instructions for Use, Without Deploying an Endovascular Graft

Figs. 17A through 17C show a representative embodiment of the steps that a representative instructions for use 58 can incorporate or direct, without deploying an endovascular graft 12.

1. Deploy Endovascular Staples to Close an Aortic Dissection

In a representative embodiment, the instructions for use 58 may include the achievement of percutaneous vascular access by conventional methods into the femoral artery, for example. In this arrangement, the patient is placed on an imaging table, allowing fluoroscopic visualization from the aortic arch to the femoral artery bifurcations. Access may be secured to one or both contralateral and ipsilateral branches by standard techniques using introducer sheaths (which can be supplied as part of the kit 40). Using fluoroscopic guidance, access to the patient's aortic arch can be achieved with an appropriately sized guide wire through one or both femoral access sites.

These steps may include, but are not limited to:

(i) placing an appropriate length and sized guide wire via the femoral access site into the aortic arch.

(ii) using fluoroscopic guidance, advancing the second steerable endovascular guide 30B with the obturator 32 over the guide wire into a position at or

near the tear in the aortic wall (Fig. 17A). The C-shaped radiopaque marker 172B located at the distal tip of the guide tube 164B will aid in fluoroscopic visualization. Position the steerable endovascular guide system 30 at the desired location for endovascular staple implantation within a desired stapling zone on the aortic dissection. In addition, the steerable endovascular guide system 30 may be used to contact the vessel wall and apply an apposition force desired for staple deployment. The instructions may note that the endovascular staples should be evenly distributed around the tear of the vessel wall in order to close the entrance of the dissection to blood flow;

(iii) removing the guide wire and obturator 32 to open the lumen 168B of the second steerable endovascular guide 30B and inserting the guide tube 164A of the first steerable endovascular guide 30A into the lumen 168B. (Alternatively, the first steerable endovascular guide 30A and the second steerable endovascular guide 30B may be inserted at the same time with only one obturator in the lumen 168B of the second steerable endovascular guide 30B.)

(iv) deflecting the distal segments 167A and/or 167B of the two segment steerable endovascular guide system 30 toward the first intended staple implantation area by rotating the first and/or second deflector knobs 170A, 170B to achieve one or more bends or angles, while observing with fluoroscopic guidance. The instructions may note that the C-shaped fluoroscopic markers 172A and 172B will appear as a straight line when their respective catheters are oriented laterally, as a right curve "(" when oriented anteriorly, and as a left curve ")" when oriented posteriorly. Alternatively, the manipulation of the guide system (deflecting the distal segments) can be performed after the insertion of the endovascular staple

applier;

(v) turning on the endovascular staple applier 38 by pressing one or more of the control buttons 194, 192 for a predetermined amount of time. This can initiate a self-checking sequence with audible and/or visual indicators. At the end of this sequence, the reverse indicator 202 will indicate that the endovascular staple applier 38 is ready to load the first endovascular staple 36. The instructions may note that, if at the end of the self check sequence, the error light 204 is illuminated, the endovascular staple applier 38 has encountered an error. The error can be cleared by pressing one or more of the control buttons 194,192 for a predetermined amount of time. After the error has been cleared, the self check sequence will initiate. If the error light 202 can not be cleared the endovascular staple applier 38 is not functional and should not be used;

(vi) load the staple by pressing the reverse command button 194 on the handle. While the motor 188 is running, insert the distal end of the endovascular staple applier catheter 182 into a port 210 having a precut "X" in the cover 212 of the cassette 34. The reverse indicator 202 will illuminate, and the endovascular staple will be drawn from the cassette into the distal end of the staple applier 38. When the endovascular staple 36 is loaded, an audible tone (e.g., two short beeps) will be heard, and the forward indicator 206 will illuminate. This indicates that the endovascular staple 36 is now preloaded in the staple applier 38, and the applier 38 can be removed from the cassette 34. The precut "X" in the cover 212 deforms with the insertion of the staple applier 38. The instructions may urge the physician to verify that the endovascular staple 36 is in place by visually inspecting the distal tip of the applier 38;

(vii) while stabilizing the control handle 160C or

handles 166A and 166B of the endovascular guide system 30 relative to the patient, inserting the now-loaded endovascular staple applier 38 through the hemostatic seal at the proximal end of the first steerable endovascular guide control handle 166A. The instructions may direct the physician to observe the location of the visible contrast-color tubing 198 or other indicia on the proximal end of the applier catheter 182 and to halt further insertion of the staple applier 38 when the end of the contrast-color tubing 198 registers with the insertion port/hemostatic seal on the handle of the steerable endovascular guide (as shown in Fig. 14B). This indicates that the distal end of applier catheter 182 rests a desired distance from the distal end of the guide tube 164 (as shown in Fig. 14C);

(viii)under fluoroscopic guidance, advancing the endovascular staple applier 38 through the steerable endovascular guide system 30 until the endovascular staple applier 38 emerges from the distal end of the endovascular guide system 30 and contacts the torn vessel wall. Slowly, continue to advance the endovascular staple applier 38 until resistance is felt, and/or visual indication of apposition can be seen using fluoroscopy. This indicates that the endovascular staple applier 38 is firmly pushing against the vessel wall at the desired location for staple deployment, and that the nested first and second steerable endovascular guide tubes 164A and 164B are firmly pushing against the generally opposite vessel wall and applying the apposition force desired for staple deployment. This resolution of force can be applied with either the staple applier 38 or endovascular guide system 30 alone, or in combination to deflect a portion or portions of the vessel wall at the desired location.

(ix) using the control handle 184 of the

endovascular staple applier 38, pressing the forward control button 192 for achieving the first stage of endovascular staple deployment. The endovascular staple will partially deploy and pause. An audible tone may be heard (e.g., four beeps) and the forward and reverse indicator 202 and 206 will illuminate (e.g., alternatively blink), indicating that the operator may continue deployment or withdraw the endovascular staple 36 back into the applier 38. The instructions may note that, in the event of a power loss when the staple 36 is partially deployed, the staple may be removed manually, for example, by manually rotating the handle 184 and catheter 182 in a counter-clockwise direction until the staple 36 disengages from the tissue. The staple applier 38 can be removed from the endovascular guide 30 in this condition;

(x) if the endovascular staple 36 is not in the desired location, pressing the reverse control button 194 re-houses the staple 36 inside the staple applier 38 for re-positioning;

(xi) if the endovascular staple 36 is in the desired position, completing the final stage of staple deployment by pressing the forward control button 192 to implant the endovascular staple 36 into the vessel wall (Fig. 17B). When complete, an audible tone (e.g., three beeps) is heard and the reverse indicator 202 will illuminate;

(xii) remove the endovascular staple applier 38, leaving the steerable endovascular guide system 30 in place;

(xiii) as needed, the steerable endovascular guide and/or the staple applier can be flushed with heparinized saline to prevent clotting in the lumens;

(xiv) identifying a port 210 having a precut "X" in the cover 212 to locate the next available endovascular staple port. Load the next endovascular staple in the

manner described above;

(xv) repositioning the steerable endovascular guide system 30 to the next desired implantation site for an endovascular staple 36. Desirably, the physician straightens the first segment 167A and second segment 167B of the steerable endovascular guide system 30 between rotating in within the endovascular graft 12, to prevent accidental dislodgment of previously deployed staples or unnecessary contact with the vessel wall;

(xvi) deploying the next endovascular staple 36 through the steerable endovascular guide 30 in the manner described above;

(xvii) after deployment of the last endovascular staple, removing the endovascular stapler applier 38 from the steerable endovascular guide system 30;

(xviii) removing the steerable endovascular guide system 30 by first re-advancing the obturator 32 and guide wire (if appropriate) into the steerable endovascular guide system 30.

2. Completion of the Procedure

The instructions for use 58 may next include the completion of the procedure. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include, but are not limited to:

(i) performing post-implant aortic angiography to evaluate the staple(s) implantation;

(ii) checking for endovascular leaks around the tear in the vessel wall. If a leak is observed, standard endovascular techniques can be used to resolve. Additional staples may be placed, in the manner described above;

(iii) removing the guide wire and femoral access sheath and close the femoral arteriotomies according to standard practice to complete the procedure (Fig. 17C).

It is to be appreciated that the general steps just described do not necessarily need to follow the order in which they were described.

F. Alternative Graft Configurations

The systems and methods described herein may be used to implant an endovascular graft having one or more extensions 13, as can be seen in Fig. 18A and 18B. Extensions 13 may be secured to the graft 12, or other extensions 13, using interlocking stents, for example. Or, the stapling system 16 may be used to apply a staple 36 at an overlap. The staple 36 may pierce the overlapped graft segments of graft 12 and extension 13, and further may pierce into tissue, or, the tissue may not be pierced.

Fig. 18A shows one embodiment of a graft 12 including one or more extensions 13. In this embodiment, the graft 12 may be implanted first in the desired region of the vessel. Successive extensions may then be coupled to the graft 12 and/or a previously placed extension 13. This may be repeated until the aorta is covered from the desired proximal to distal landing zones. As can be seen, the proximal portion of the distal most two extensions 13 are shown as positioned inside of the graft/extension proximal to each extension.

Fig. 18B shows an alternative embodiment where the proximal portion of the distal most two extensions 13 are shown as positioned exterior to the outer diameter of the graft/extension proximal to each extension. In this embodiment, the first distal extension 13 may be placed at or above the level of the celiac artery, for example. The column strength and/or radial expansion of the extension 13 may allow it to remain in position. One or more additional extensions 13 may be deployed further proximal to the first extension 13 with the distal portion of the second extension positioned inside of the

proximal portion of the second extension 13 (or the graft 12) to extend the graft further proximal in the vessel. This may be repeated until the aorta is covered from the desired distal to proximal landing zones.

It will be appreciated that the components and/or features of the preferred embodiments described herein may be used together or separately, while the depicted methods and devices may be combined or modified in whole or in part. It is contemplated that the components of the guiding device, fastener device, and helical fastener may be alternately oriented relative to each other, for example, offset, bi-axial, etc. Further, it will be understood that the various embodiments may be used in additional procedures not described herein, such as vascular trauma, arterial dissections, artificial heart valve attachment and attachment of other prosthetic device within the vascular system and generally within the body.

The foregoing is considered as illustrative only of the principles of the invention. Furthermore, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

I Claim:

1. A system for modifying a prosthesis to conform to a vessel wall comprising:

a catheter system sized and configured for introduction to a targeted site in the vessel,

the catheter system adapted to apply a resolution of force to the prosthesis to modify the shape of the prosthesis to conform the shape of the prosthesis to the shape of the vessel wall, and

the catheter system adapted to position a fastener in at least one region of the prosthesis to maintain the conformed shape of the prosthesis to the vessel wall.

2. A system according to Claim 1:

wherein the catheter system is adapted to push against the prosthesis and against the vessel wall at the desired fastener position, and the catheter system is adapted to push against the generally opposite vessel wall for application of the resolution of force for fastener position.

3. A system according to Claim 1:

wherein the catheter system further includes a lumen for passage of an endovascular device to the targeted site in the vessel.

4. A system according to Claim 3:

further including a fastening device sized and configured for introduction through the catheter system lumen to the targeted site in the vessel.

5. A system according to Claim 4:

wherein the fastening device includes an actuator to deploy the fastener in at least one region of the prosthesis to maintain the conformed shape of the prosthesis to the vessel wall.

6. A system according to Claim 1:

wherein the catheter system comprises a steerable guide device.

7. A system according to Claim 6:

wherein the steerable guide device comprises a distal portion adapted to deflect in at least a first position.

8. A system according to Claim 6:

wherein the steerable guide device comprises a distal portion adapted to deflect in at least a first position and a second position.

9. A system according to Claim 8:

wherein the second position is different than the first position.

10. A system according to Claim 8:

wherein the steerable guide device comprises a first steerable guide and a second steerable guide.

11. A method of modifying a prosthesis to conform to a vessel wall comprising:

providing a catheter system sized and configured for introduction to a targeted site in the vessel,

introducing into the vessel the catheter system,

advancing the catheter system to the targeted site in the vessel,

positioning a distal end of the catheter system against the prosthesis,

positioning a distal portion of the catheter system against the prosthesis or vessel wall away from the distal end,

continuing to advance the catheter system until the catheter system is applying a resolution of force to the prosthesis and modifying the shape of the prosthesis and conforming the shape of the prosthesis to the vessel wall, and

deploying a staple in at least one region of the prosthesis, the staple maintaining the conforming shape of the prosthesis to the vessel wall.

12. A method according to Claim 11:

further including providing a staple applier sized and configured for introduction through a catheter system lumen to the targeted site in the vessel, the staple applier including an actuator for deploying the staple in at least one region of the prosthesis for maintaining the shape of the prosthesis to the vessel wall.

13. A system for modifying a prosthesis to conform to a vessel wall comprising:

a steerable guide device sized and configured for introduction to a targeted site in the vessel, the steerable guide device including a lumen for passage of an endovascular device to the targeted site in the vessel,

a fastening device sized and configured for introduction through the steerable guide device lumen to the targeted site in the vessel,

the steerable guide device adapted to apply a resolution of force to the prosthesis to modify the shape of the prosthesis to conform the shape of the prosthesis to the vessel wall, and

the fastening device including an actuator to deploy a fastener in at least one region of the prosthesis to maintain the conformed shape of the prosthesis to the vessel wall.

14. A method of modifying a prosthesis to conform to a vessel wall comprising:

providing a steerable guide device sized and configured for introduction to a targeted site in the vessel, the steerable guide device including a lumen for passage of an endovascular device to the targeted site in the vessel,

providing a staple applier sized and configured for introduction through the steerable guide device lumen to the targeted site in the vessel, the staple applier including an actuator for deploying a staple in at least

one region of the prosthesis for maintaining the shape of the prosthesis to the vessel wall,

introducing into the vessel the steerable guide device,

advancing the steerable guide device to the targeted site in the vessel,

positioning a distal end of the steerable guide device against the prosthesis,

positioning a distal portion of the steerable guide device against the prosthesis or vessel wall away from the distal end,

advancing the staple applier through the steerable guide device lumen until the staple applier emerges from the distal end of the steerable guide device and contacts the prosthesis,

continuing to advance the staple applier until the staple applier is applying a resolution of force to the prosthesis and modifying the shape of the prosthesis and conforming the shape of the prosthesis to the vessel wall, and

deploying a staple in at least one region of the prosthesis, the staple maintaining the conforming shape of the prosthesis to the vessel wall.

15. A method of modifying a prosthesis comprising:

providing a prosthesis adapted for endovascular delivery and implantation, the prosthesis including a delivery shape and a deployed shape,

delivering the prosthesis to a target site,

deploying the prosthesis at the target site causing the prosthesis to change shape from the delivery shape to the deployed shape, and

manipulating the prosthesis by implanting a fastener through the prosthesis causing the prosthesis to change shape from the deployed shape to an implanted shape different from the deployed shape.

16. A method according to Claim 15:

wherein the fastener is implanted through the prosthesis and into tissue.

17. A method according to Claim 15:

wherein the implanted shape conforms to a shape of the target site.

18. A method according to Claim 17:

wherein the target site comprises a tortuous vessel.

19. A method according to Claim 15:

the prosthesis further including a proximal portion and a distal portion, and manipulating the prosthesis includes manipulating the proximal portion of the prosthesis by implanting a fastener through the proximal portion of the prosthesis causing the proximal portion of the prosthesis to change shape from the deployed shape to an implanted shape different from the deployed shape.

20. A method according to Claim 19:

wherein the prosthesis distal portion maintains its deployed shape and is not manipulated to change shape from its deployed shape to an implanted shape.

21. A catheter system comprising:

a catheter system sized and configured for introduction to a targeted site in the vessel, the catheter system adapted to apply a resolution of force to a prosthesis to modify the shape of the prosthesis to conform the shape of the prosthesis to the shape of the vessel wall,

the catheter system adapted to position a fastener in at least one region of the prosthesis to maintain the conformed shape of the prosthesis to the vessel wall, and

instructions for use describing the use of the catheter system, the instructions comprising the operations of introducing into the vessel the catheter system, advancing the catheter system to the targeted site in the vessel, positioning a distal end of the

catheter system against the prosthesis, positioning a distal portion of the catheter system against the prosthesis or vessel wall away from the distal end, continuing to advance the catheter system until the catheter system is applying a resolution of force to the prosthesis and modifying the shape of the prosthesis and conforming the shape of the prosthesis to the vessel wall, and deploying a staple in at least one region of the prosthesis, the staple maintaining the conforming shape of the prosthesis to the vessel wall.

22. A system according to Claim 21:

wherein the catheter system is adapted to push against the prosthesis and against the vessel wall at the desired fastener position, and the catheter system is adapted to push against the generally opposite vessel wall for application of the resolution of force for fastener position.

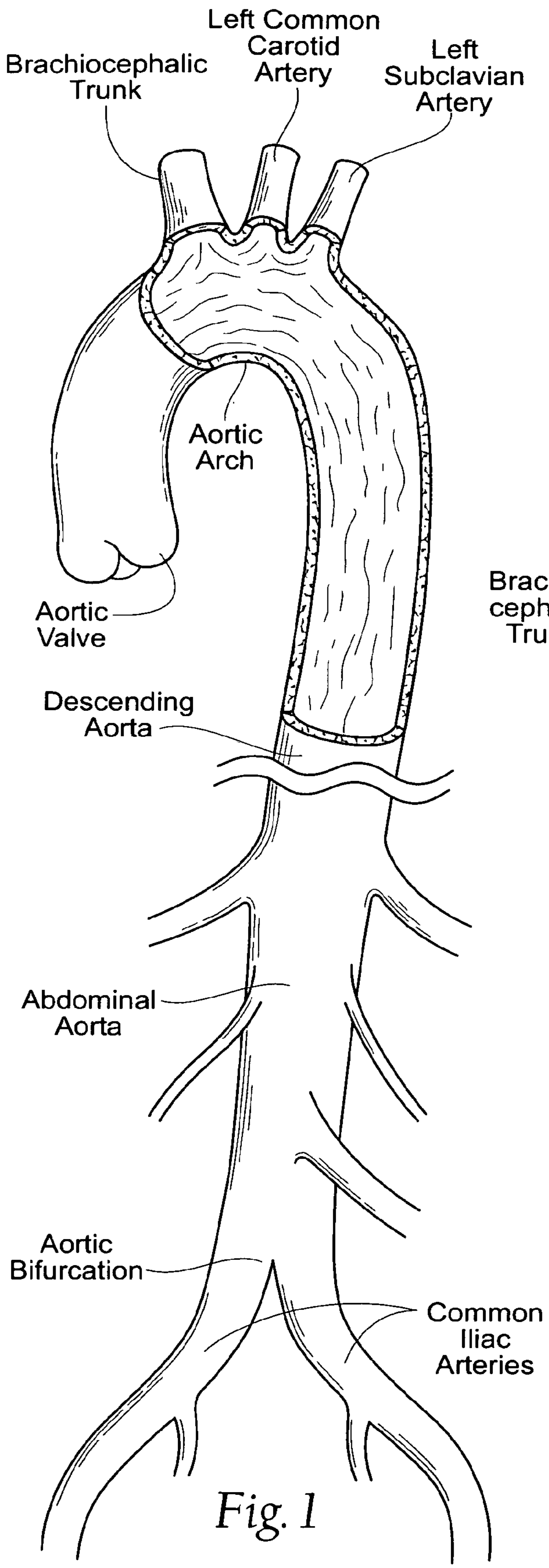

Left Common Carotid Artery
Brachiocephalic Trunk
Left Subclavian Artery
Aortic Arch
Aortic Valve
Descending Aorta
Abdominal Aorta
Aortic Bifurcation
Common Iliac Arteries

Fig. 1

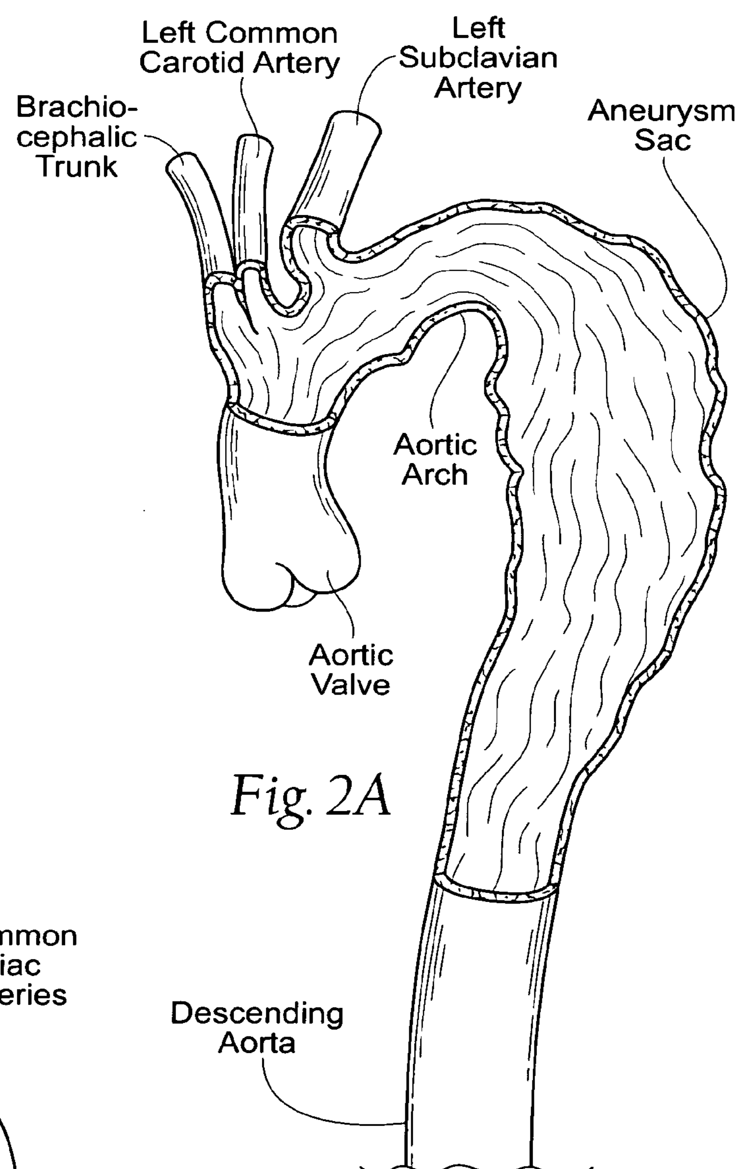

Left Common Carotid Artery
Left Subclavian Artery
Brachio-cephalic Trunk
Aneurysm Sac
Aortic Arch
Aortic Valve
Descending Aorta

Fig. 2A

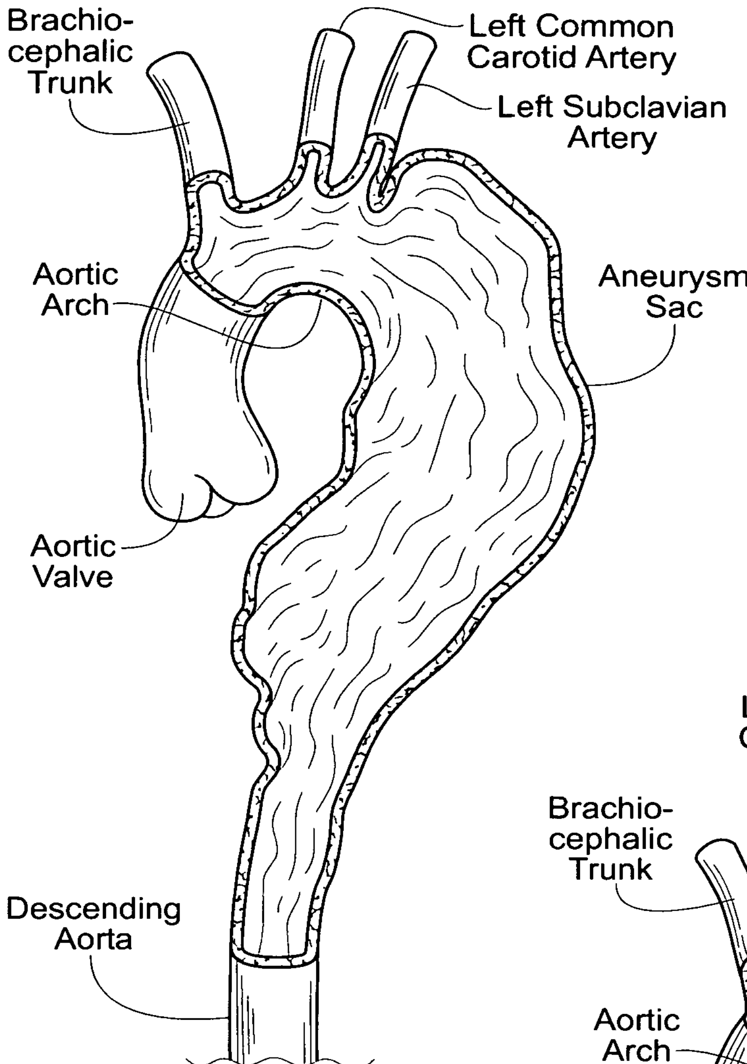

Brachio-
cephalic
Trunk
Left Common
Carotid Artery
Left Subclavian
Artery
Aortic
Arch
Aneurysm
Sac
Aortic
Valve
Descending
Aorta

Fig. 2B

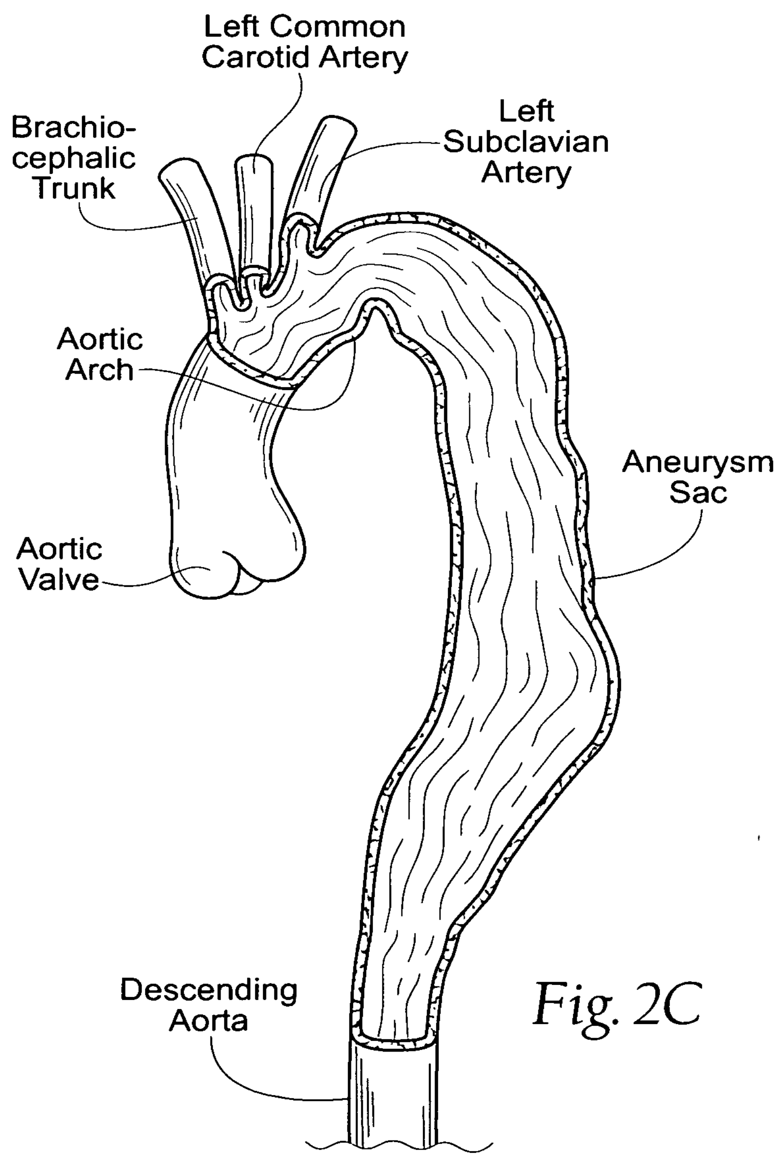
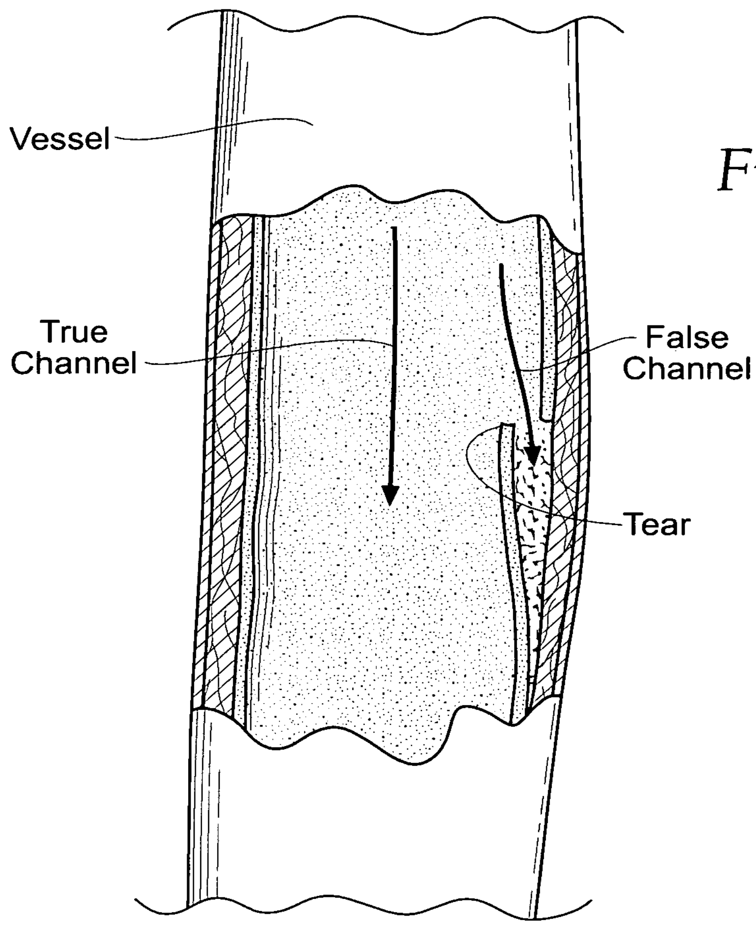

Left Common
Carotid Artery
Brachio-
cephalic
Trunk
Left
Subclavian
Artery
Aortic
Arch
Aneurysm
Sac
Aortic
Valve
Descending
Aorta

Fig. 2C


Vessel
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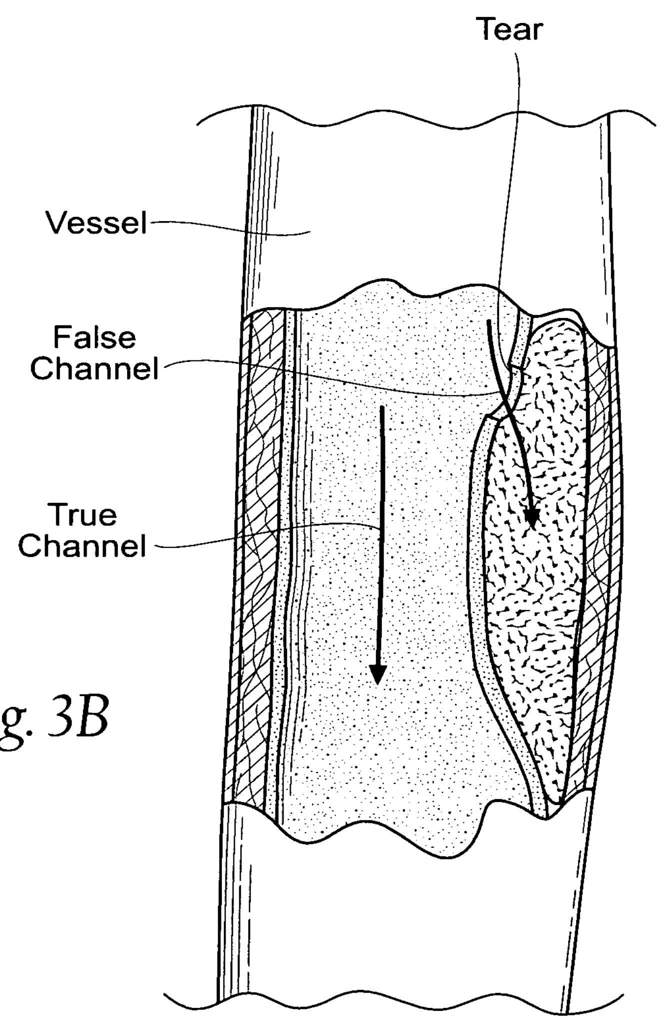
Channel
False
Channel
Tear

Fig. 3A


Tear
Vessel
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Channel
True
Channel

Fig. 3B

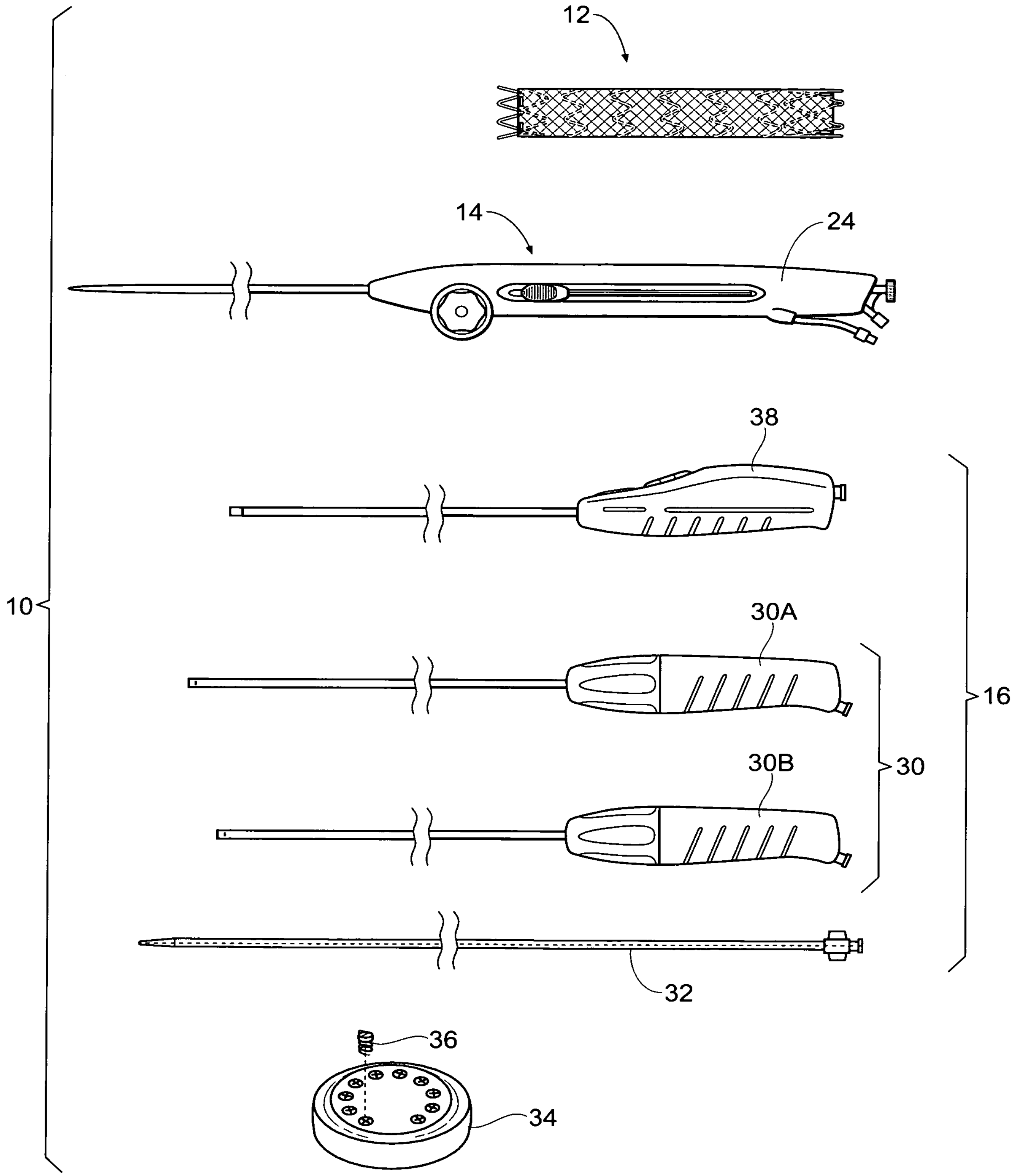


Fig. 4

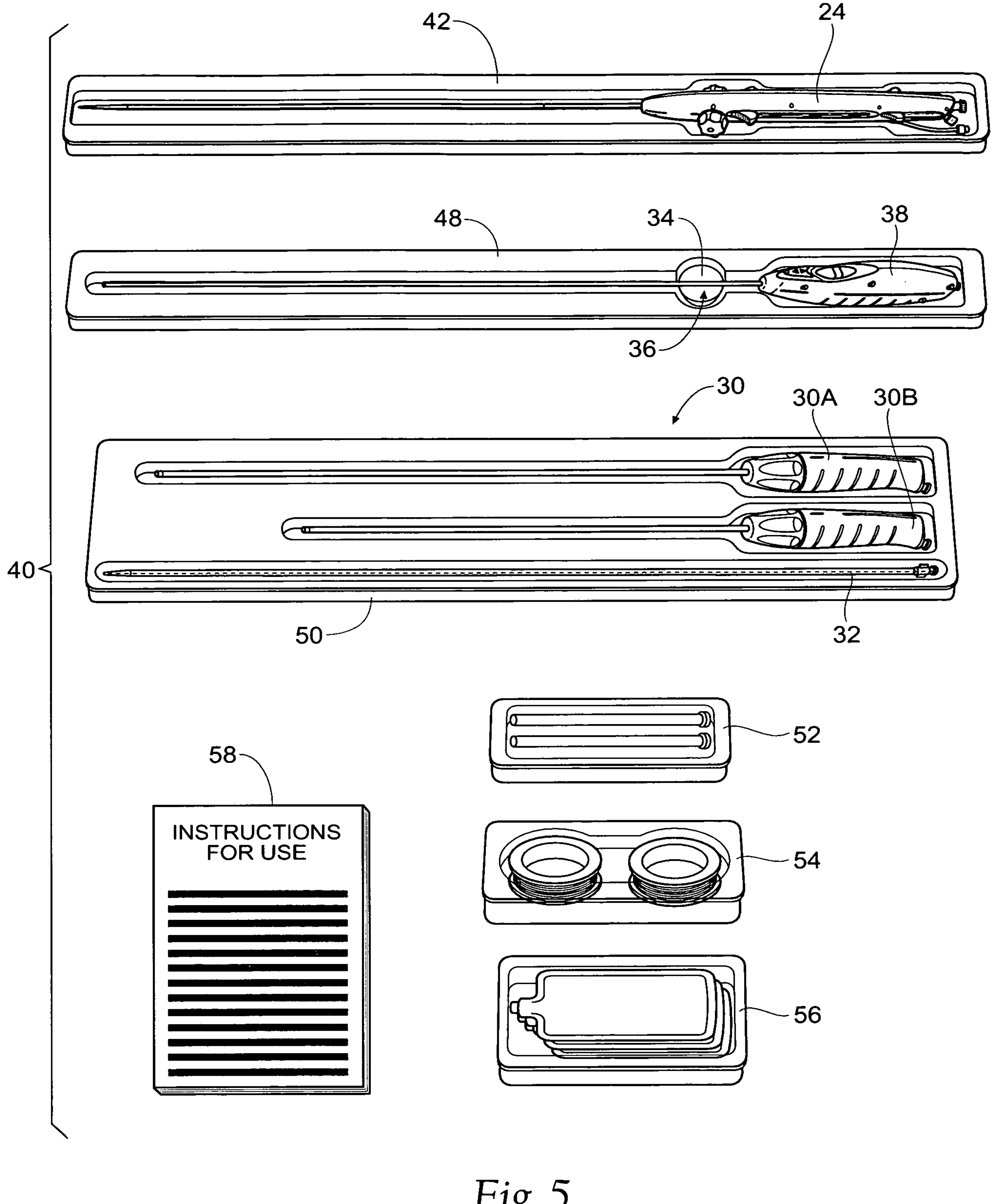

42
24
48
34
38
36
30
30A
30B
40
50
32
52
58
INSTRUCTIONS FOR USE
54
56

Fig. 5

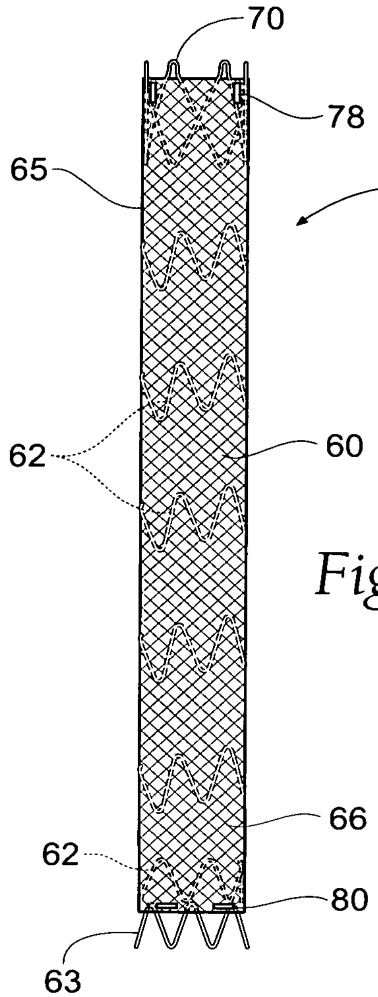


Fig. 6A

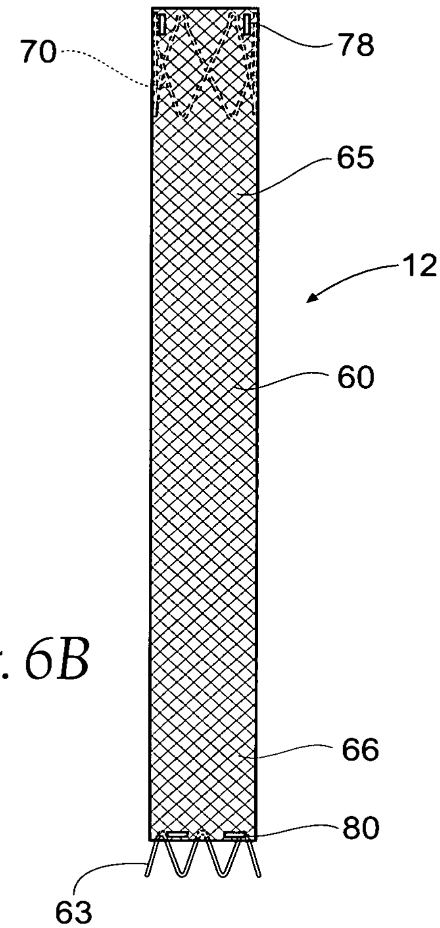


Fig. 6B

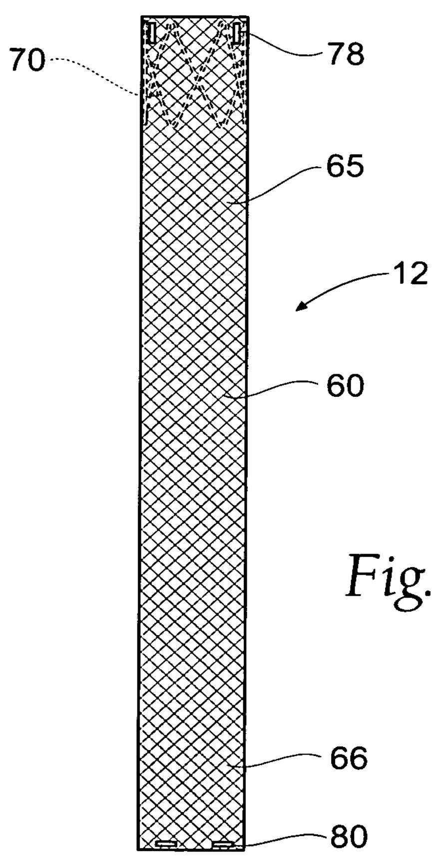


Fig. 6C

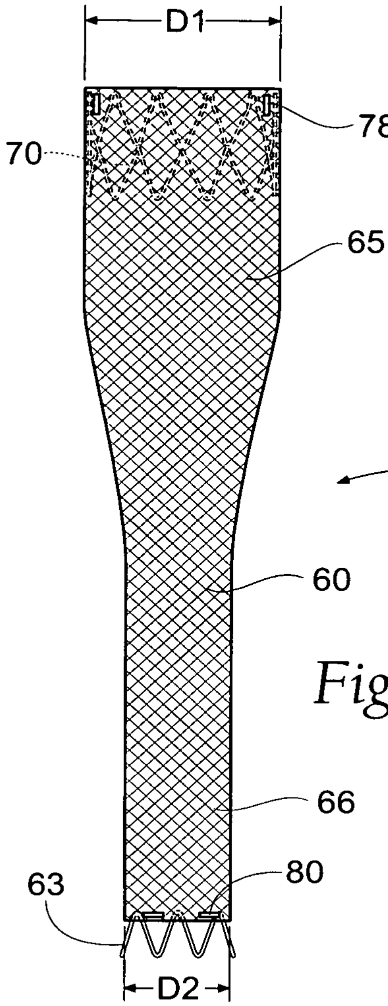


Fig. 6D

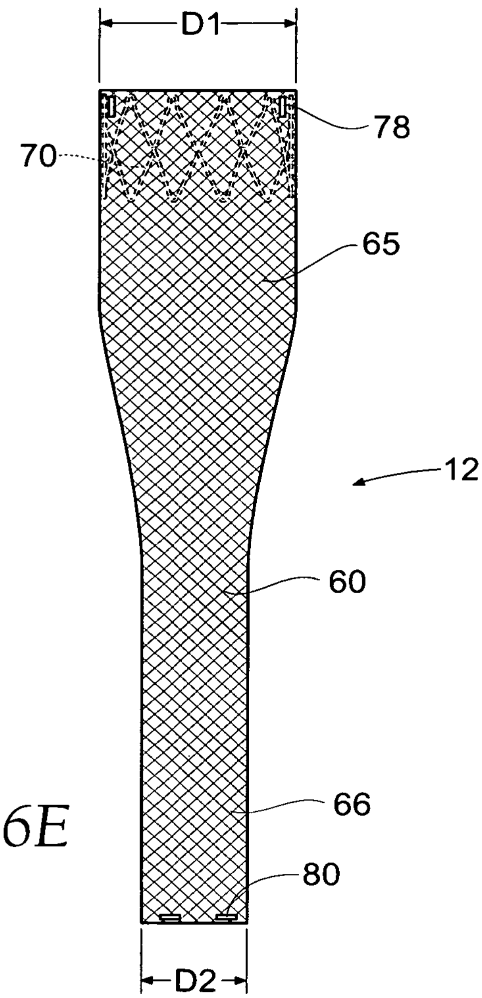


Fig. 6E

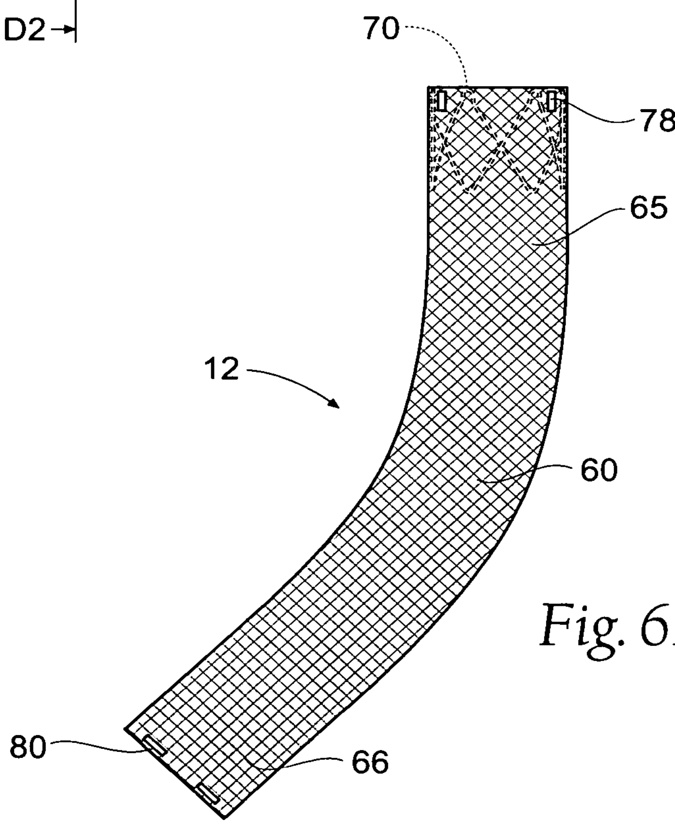


Fig. 6F

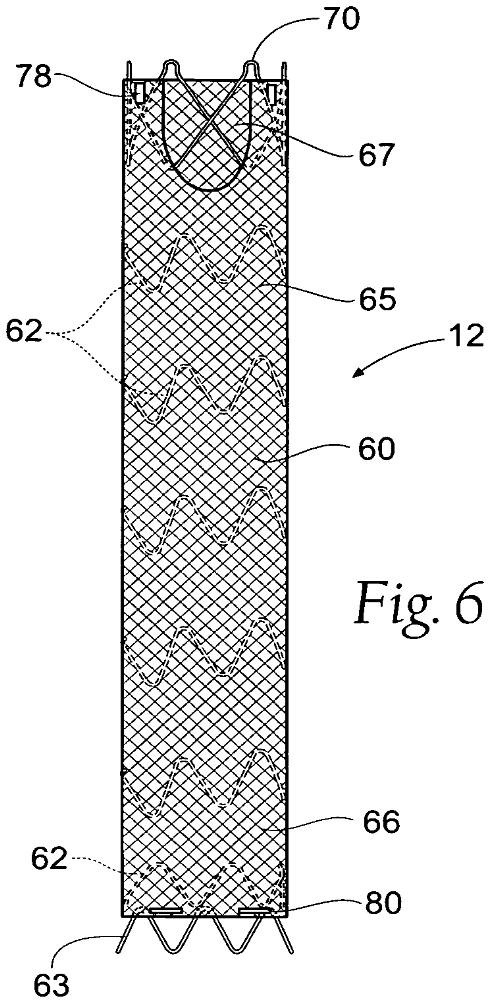


Fig. 6G

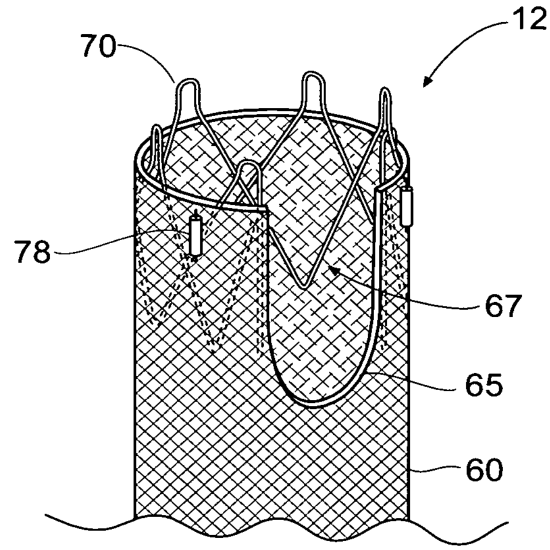


Fig. 6H

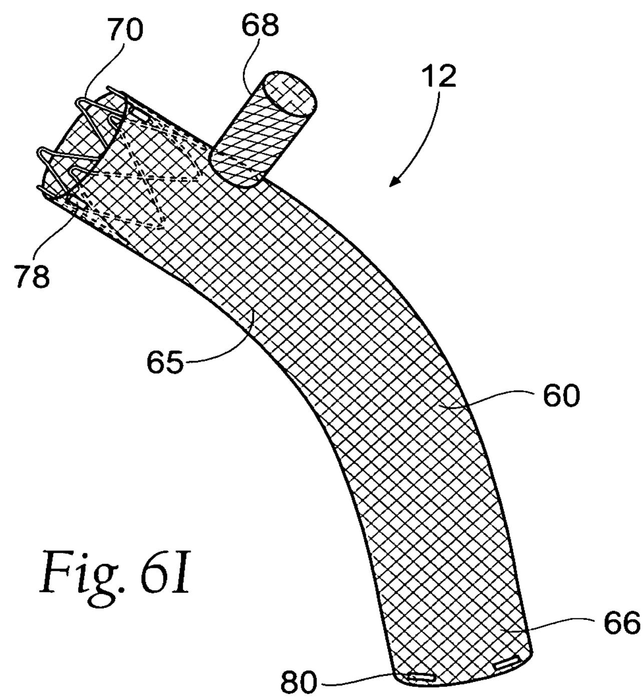


Fig. 6I

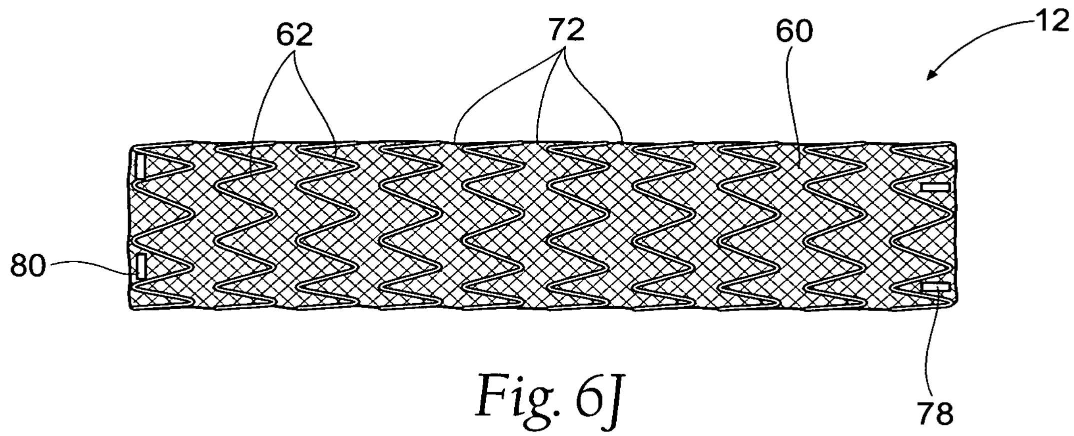

62
72
60
12
80
78

Fig. 6J

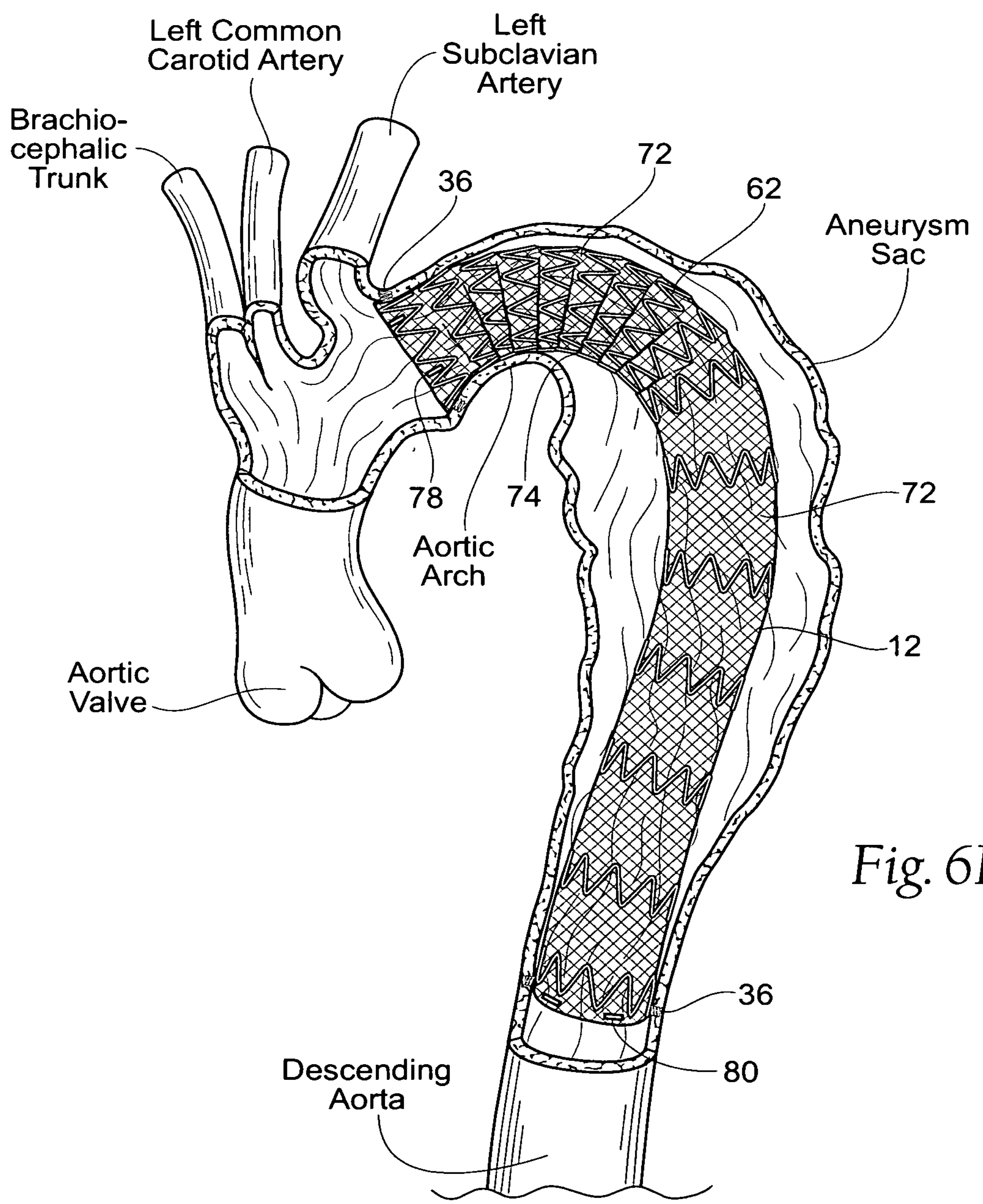

Left Common Carotid Artery
Left Subclavian Artery
Brachio-cephalic Trunk
36
72
62
Aneurysm Sac
78
74
72
Aortic Arch
12
Aortic Valve
36
80
Descending Aorta

Fig. 6K

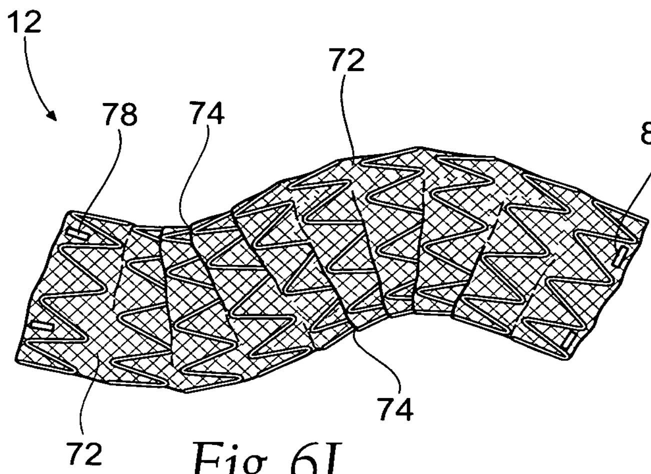


Fig. 6L

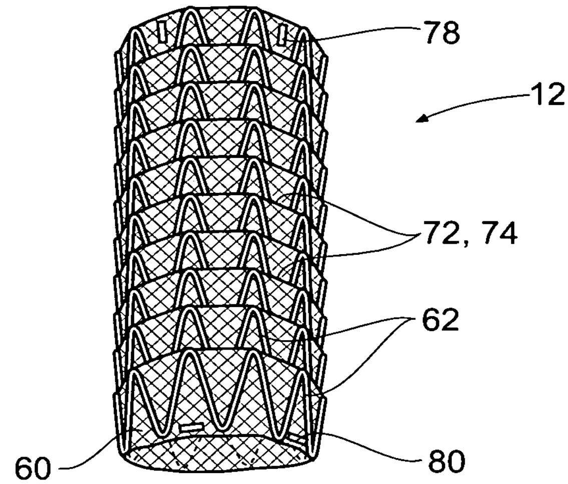


Fig. 6M

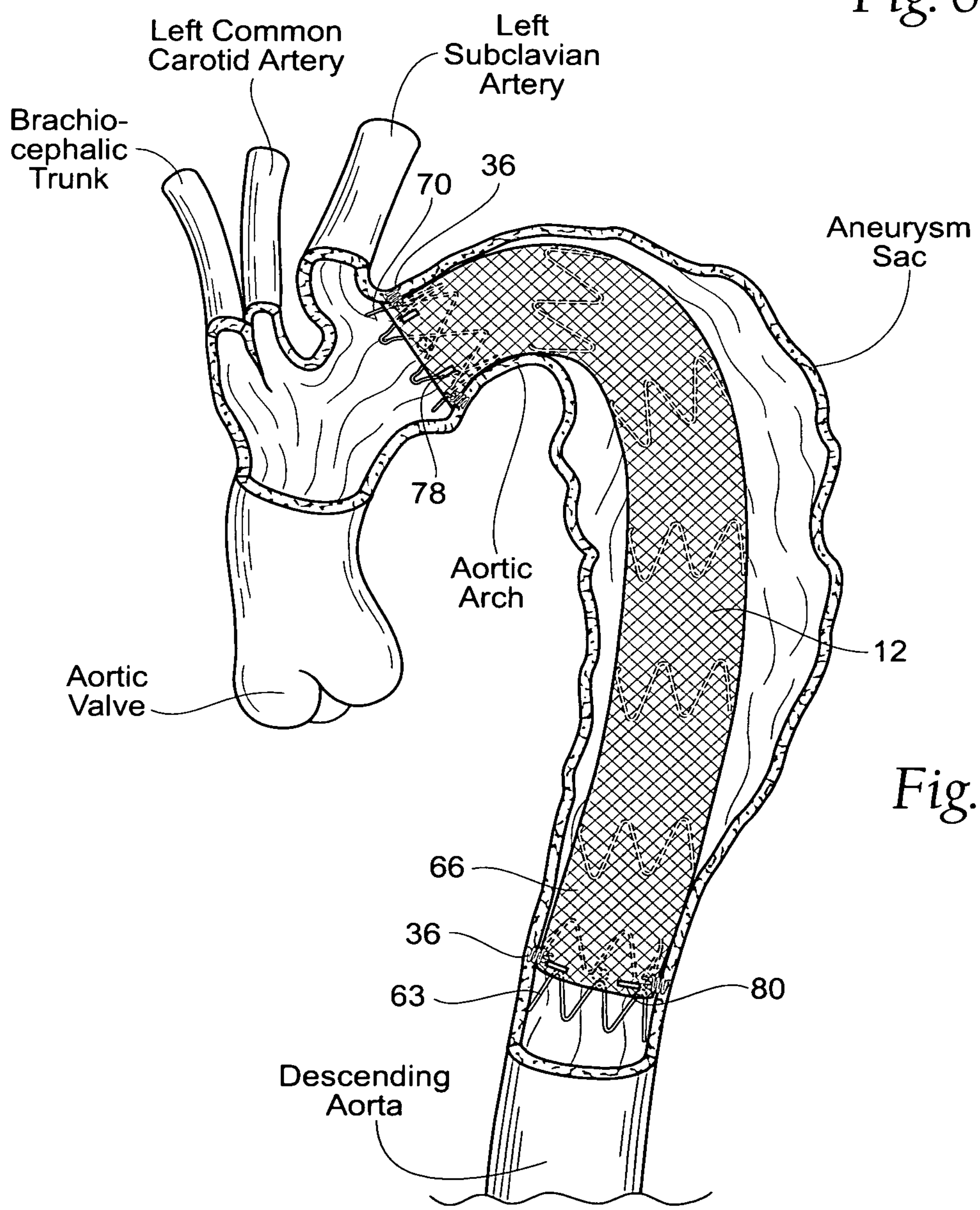


Fig. 7A

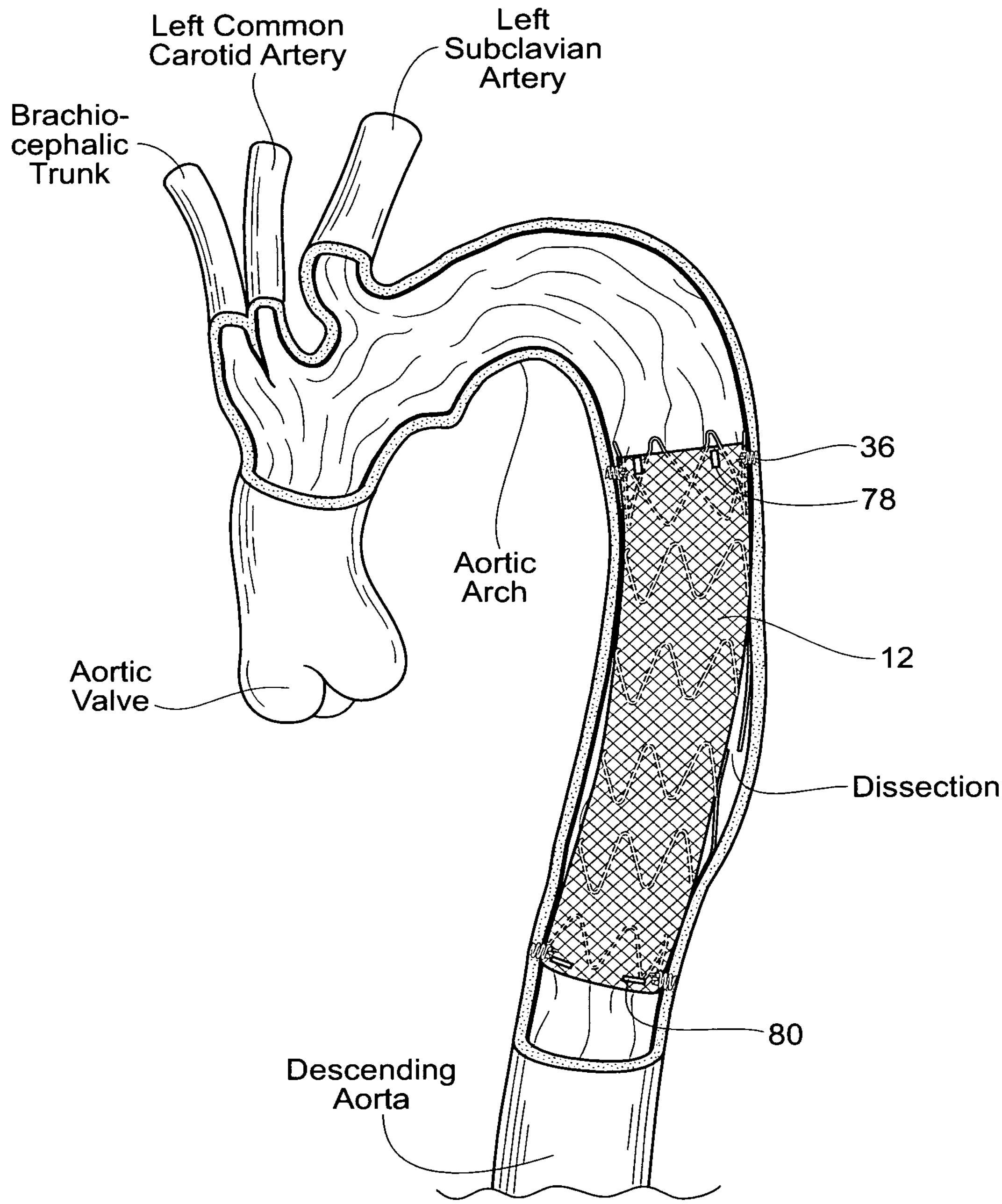

Left Common Carotid Artery
Left Subclavian Artery
Brachio-cephalic Trunk
36
78
Aortic Arch
12
Aortic Valve
Dissection
80
Descending Aorta

Fig. 7B

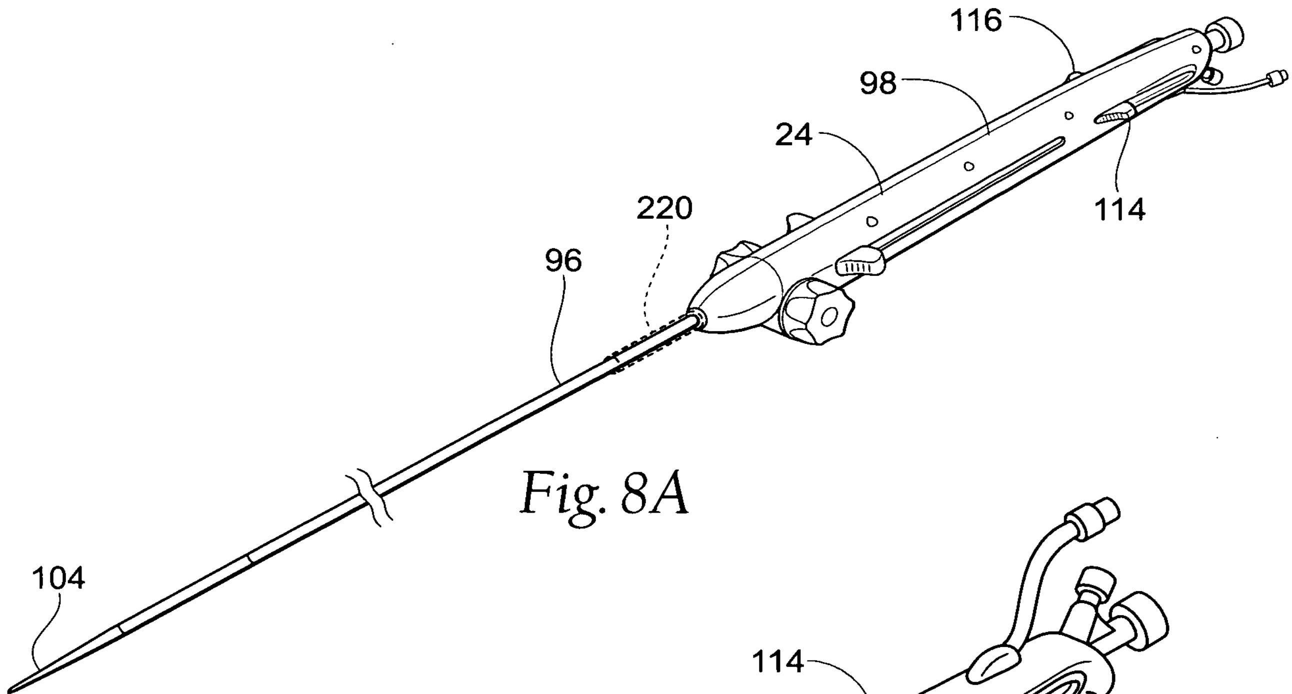


Fig. 8A

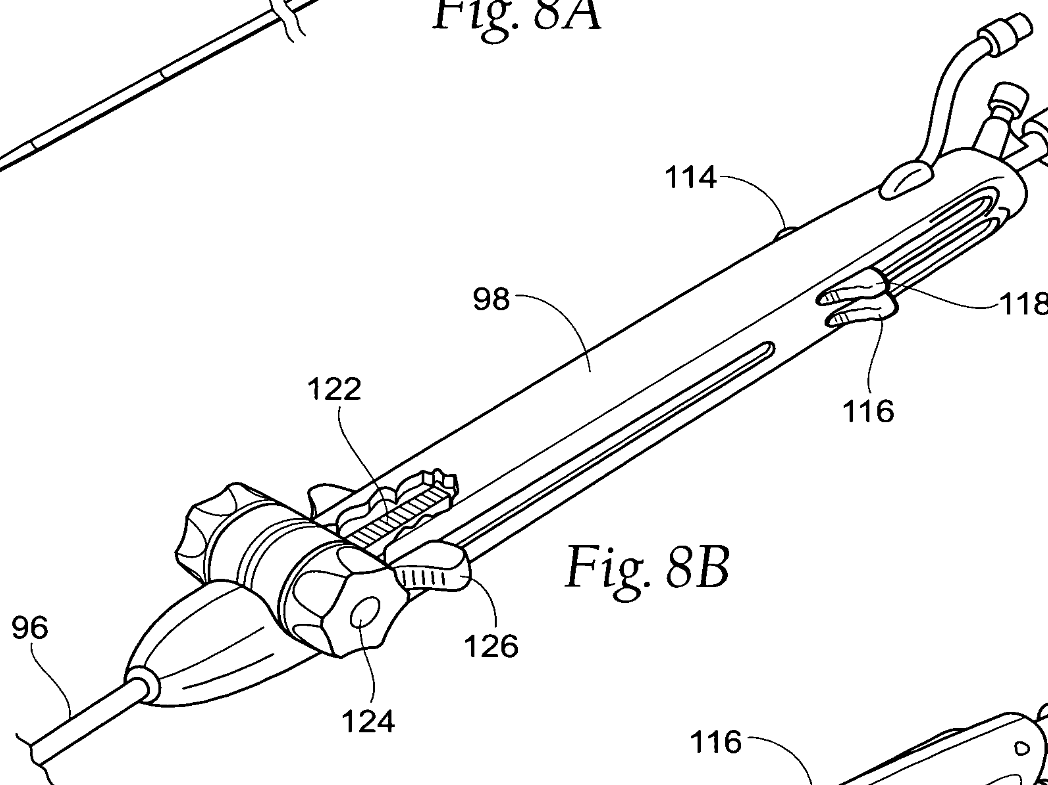


Fig. 8B

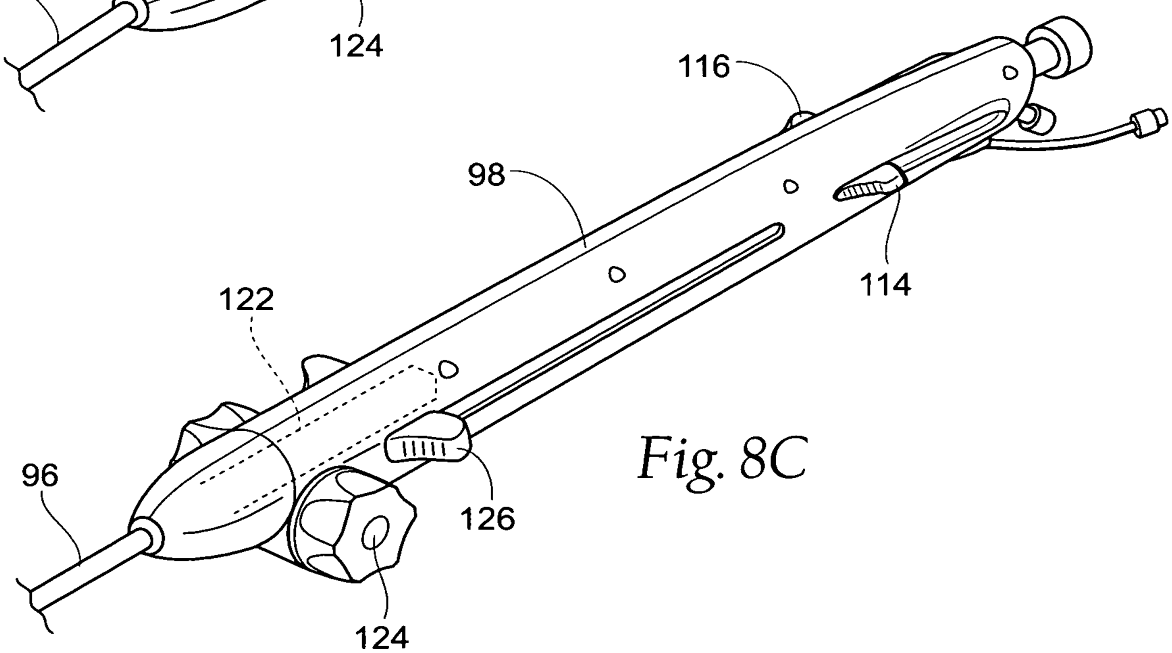


Fig. 8C

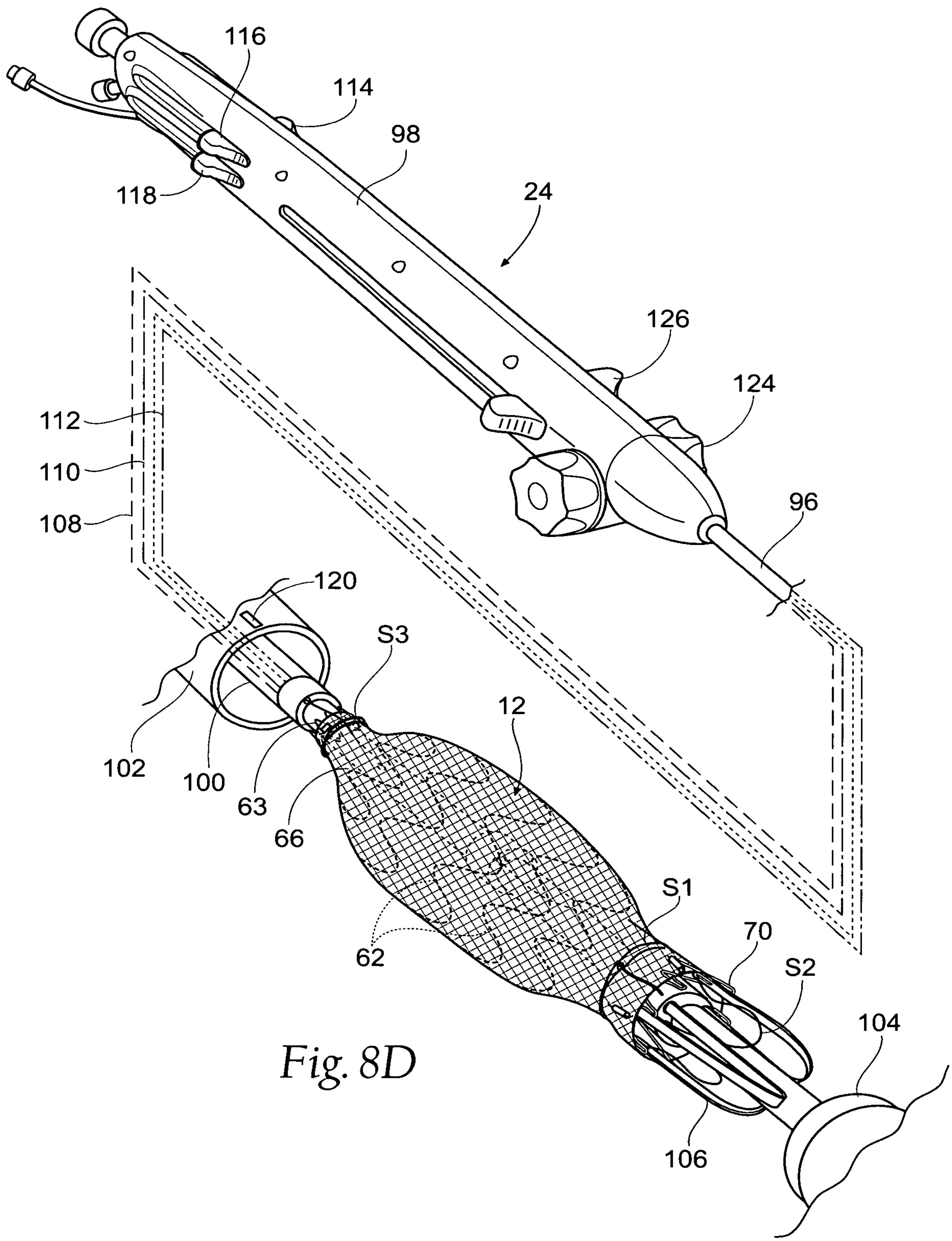

116
114
98
118
24
126
124
112
110
108
96
120
S3
12
102
100
63
66
S1
70
62
S2
104
106

Fig. 8D

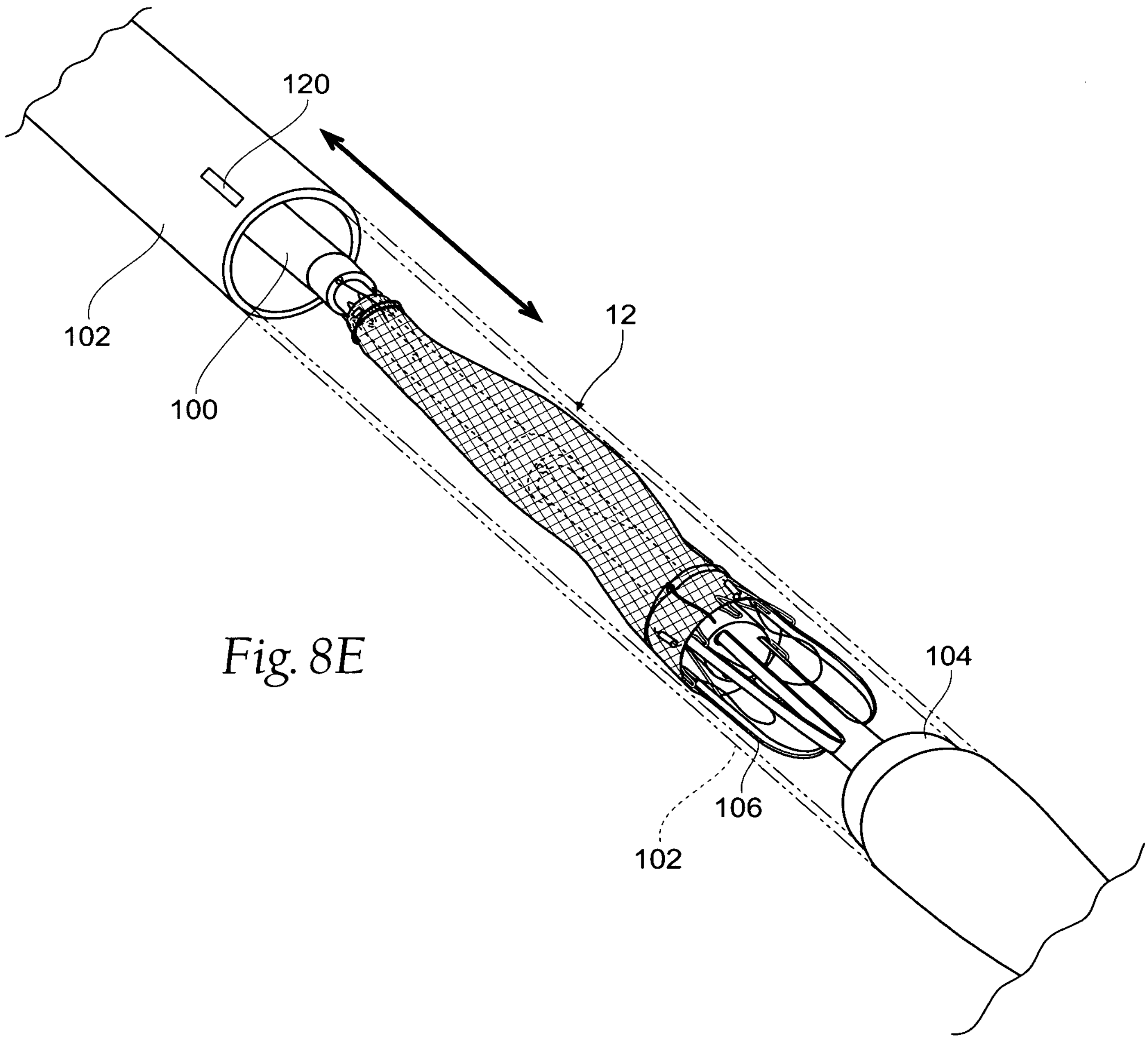


Fig. 8E

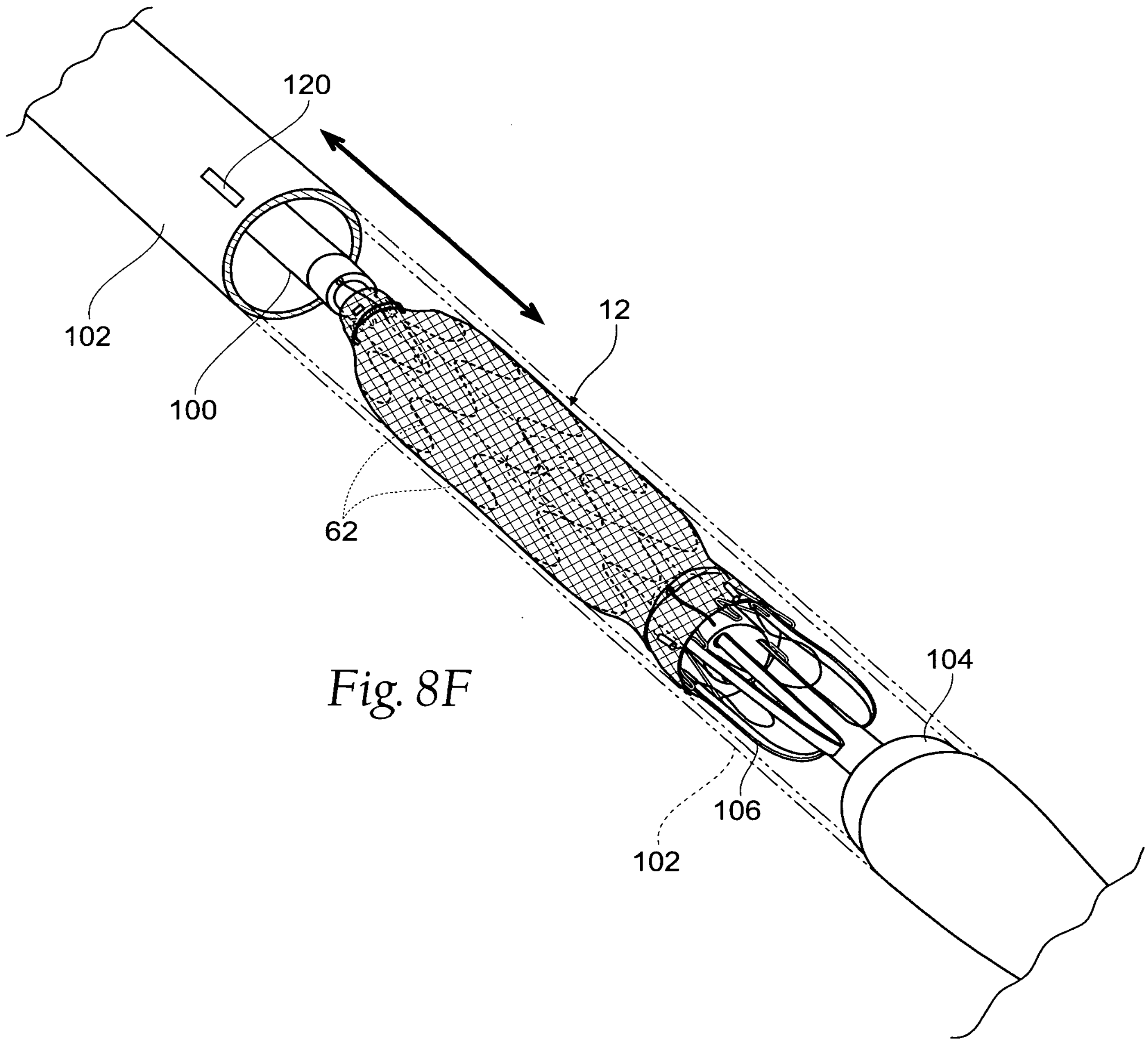


Fig. 8F

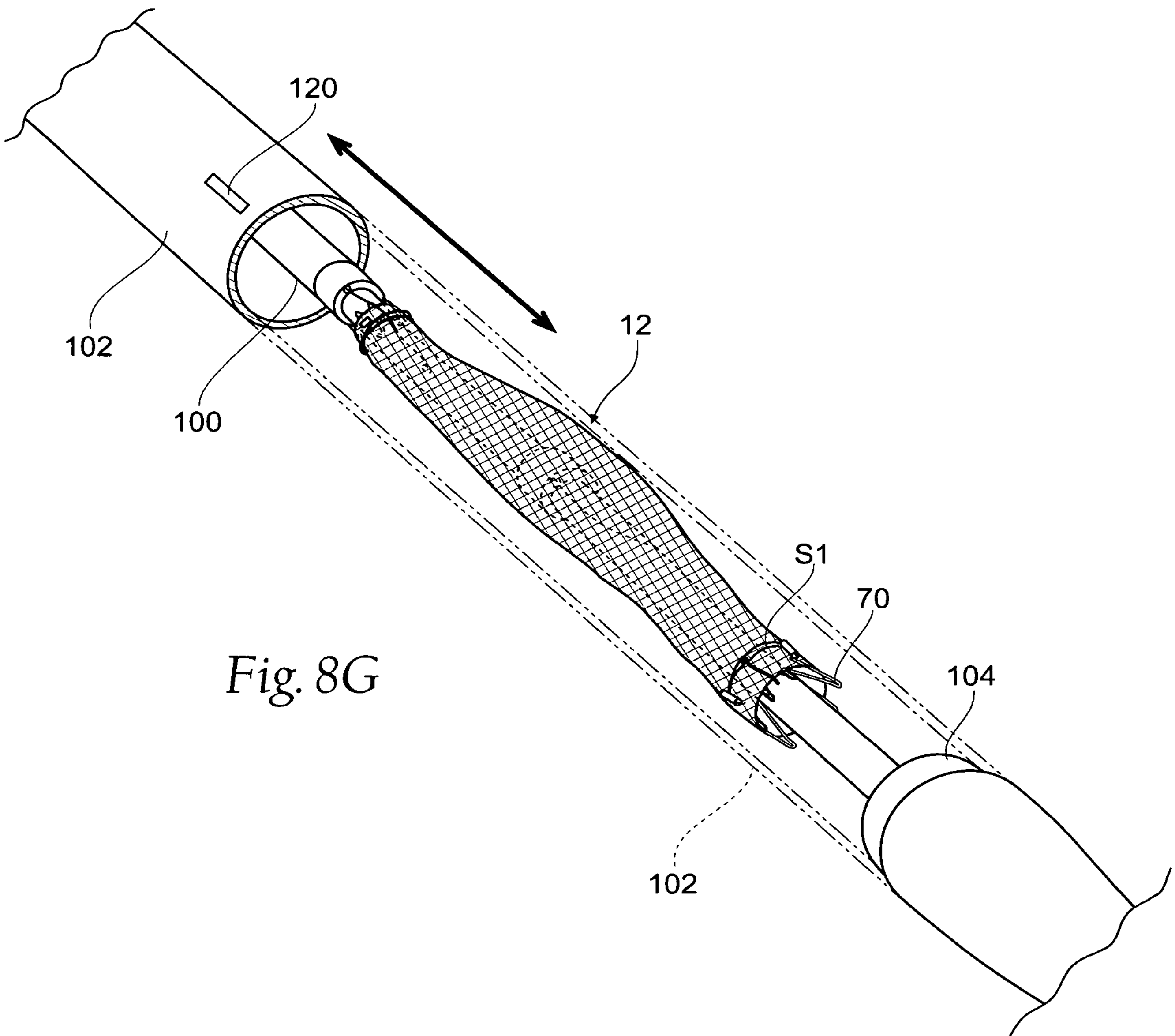


Fig. 8G

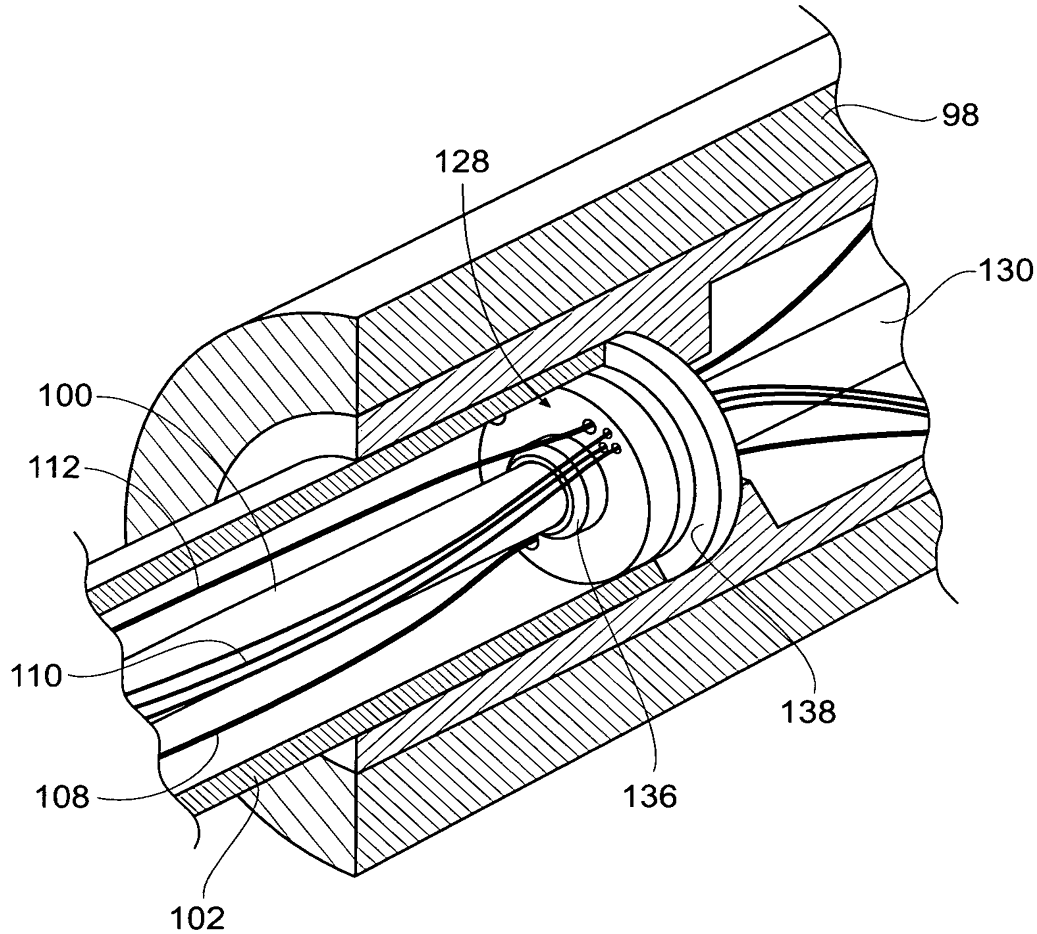


Fig. 9

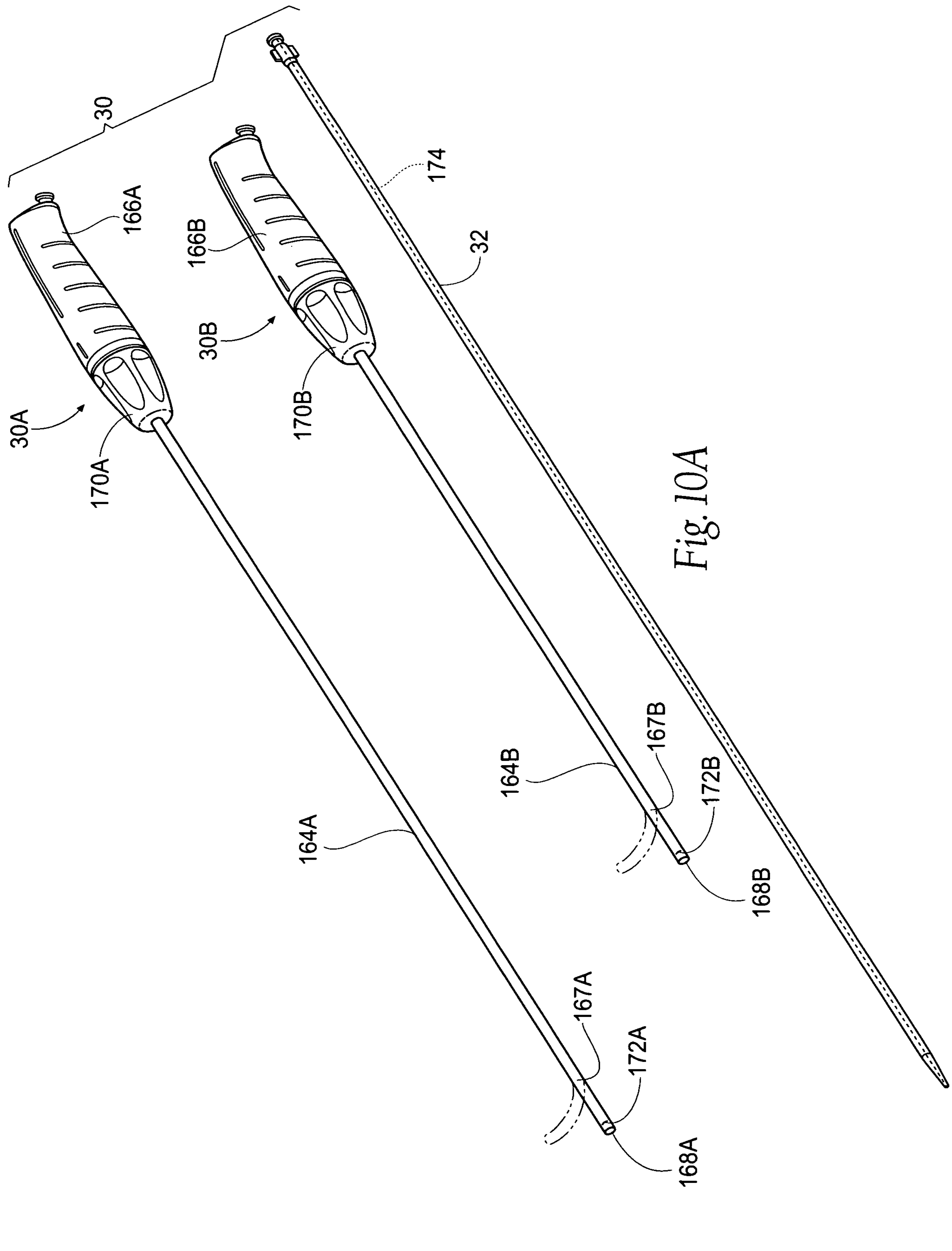

30
174
166A
166B
32
30B
30A
170B
170A
167B
164B
172B
164A
168B
167A
172A
168A

Fig. 10A

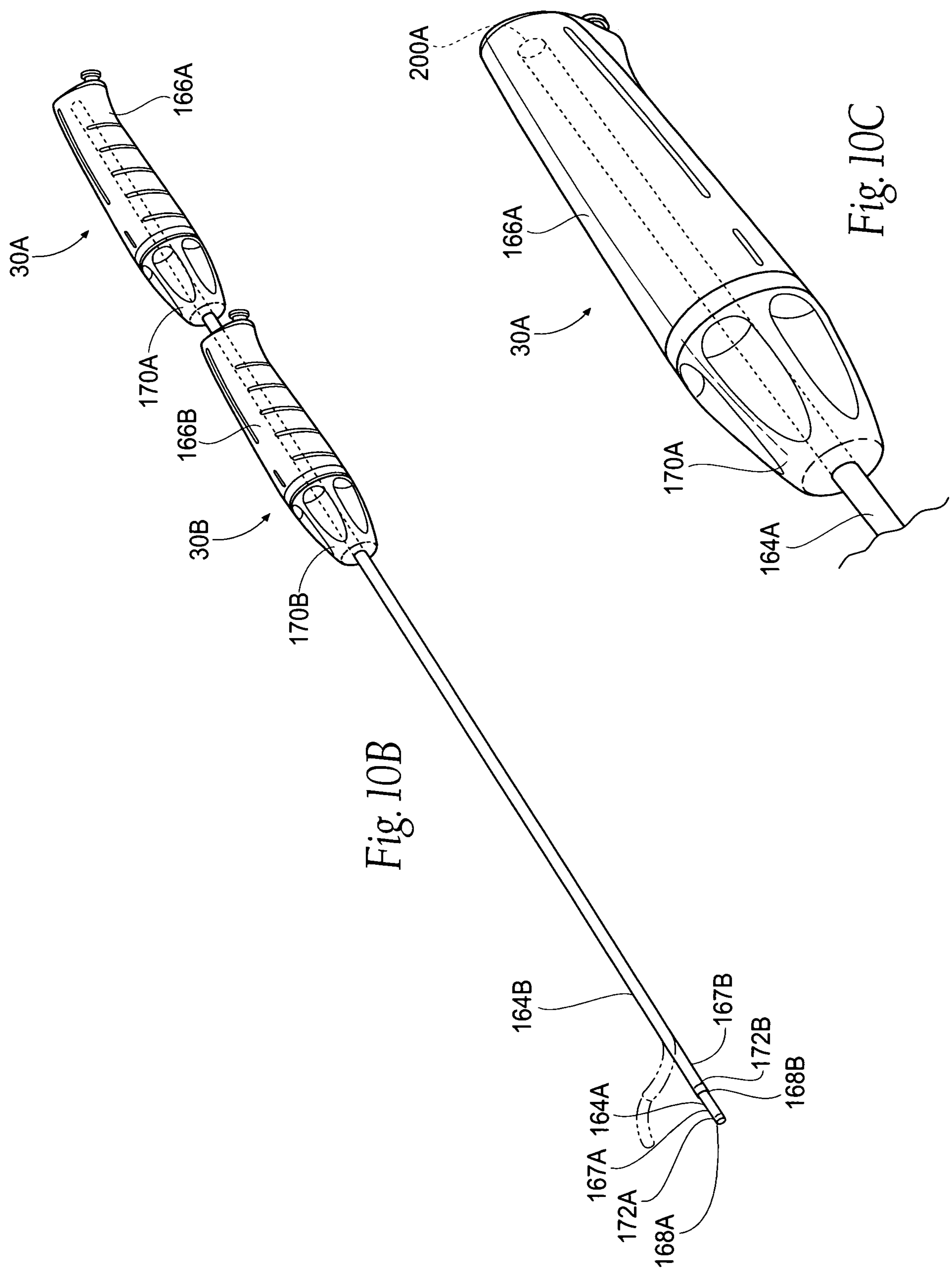


Fig. 10B

Fig. 10C

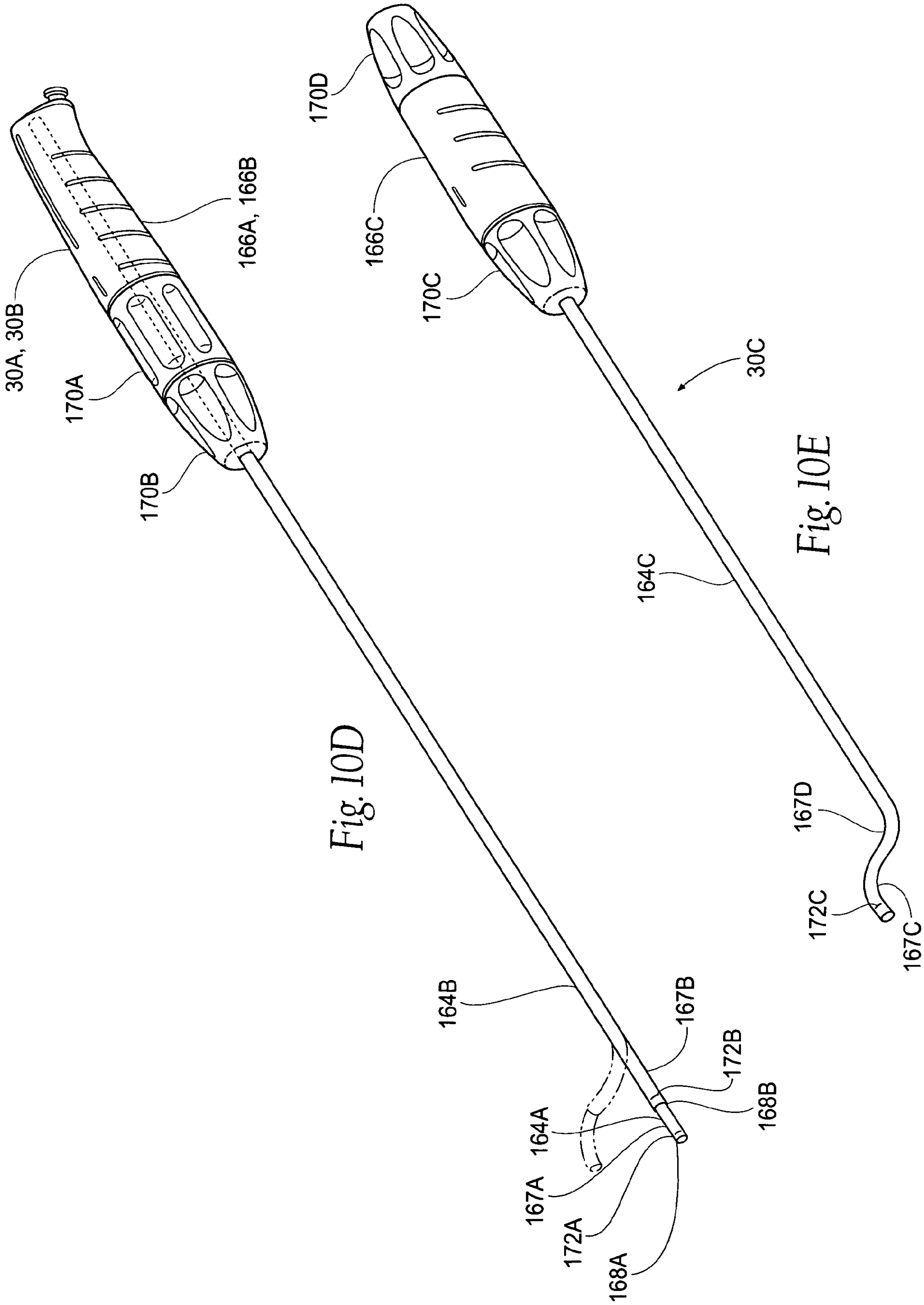


Fig. 10D

Fig. 10E

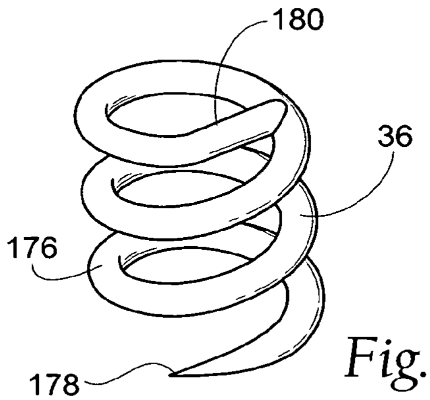


Fig. 11A

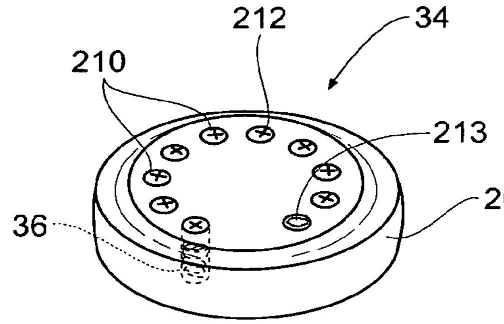


Fig. 11B

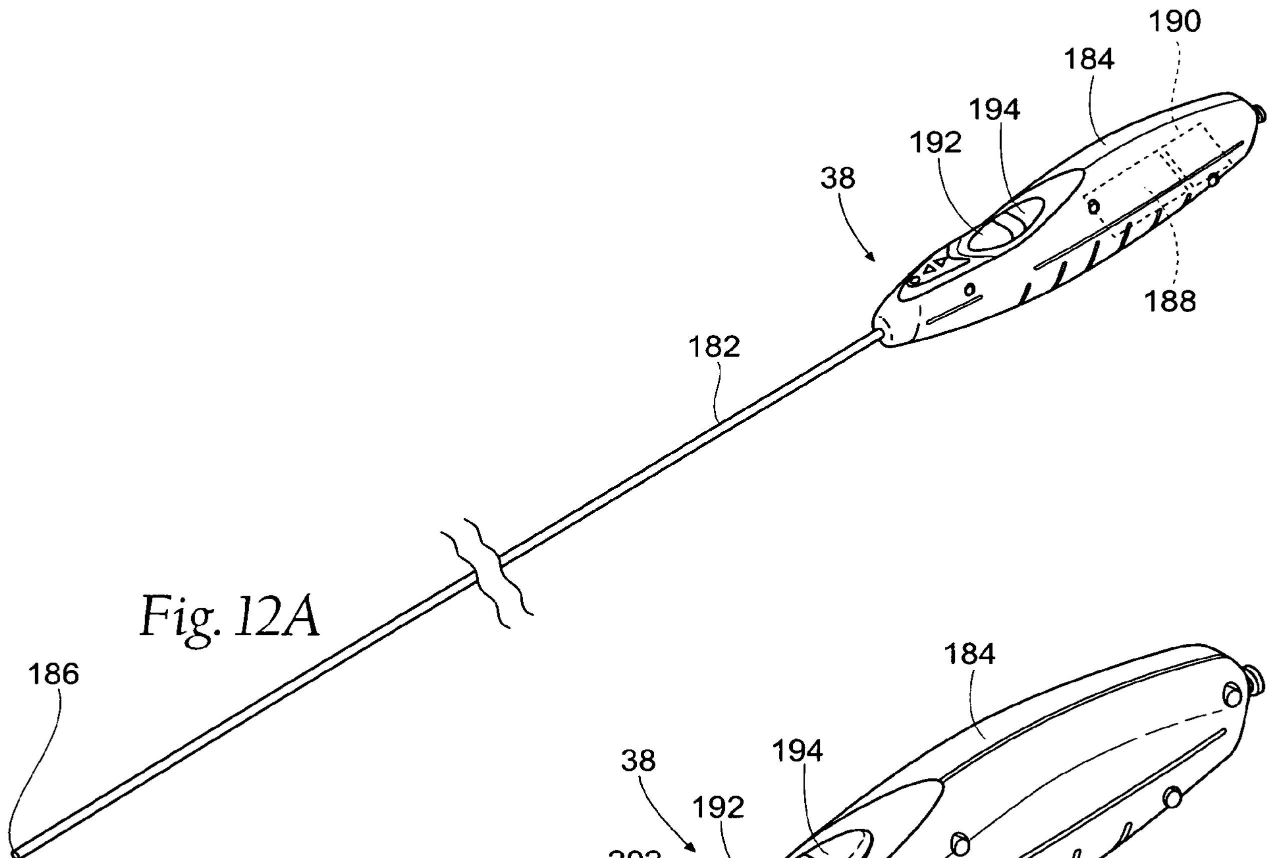


Fig. 12A

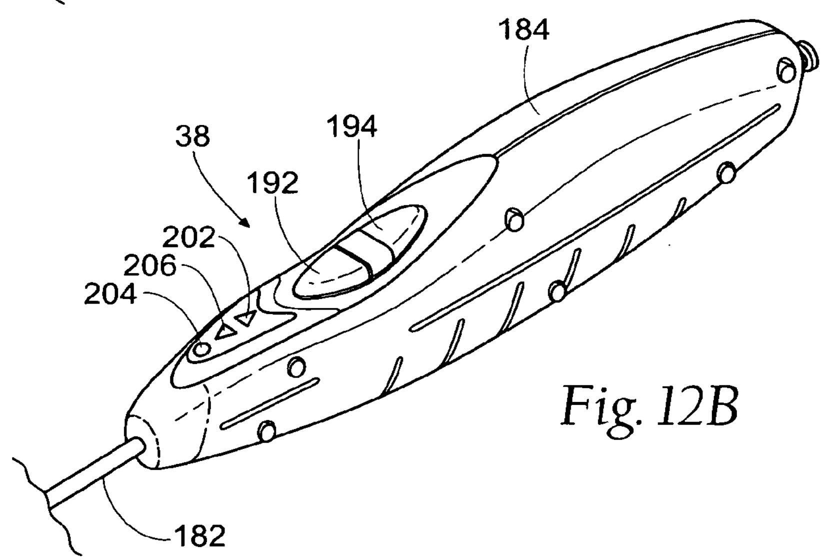


Fig. 12B

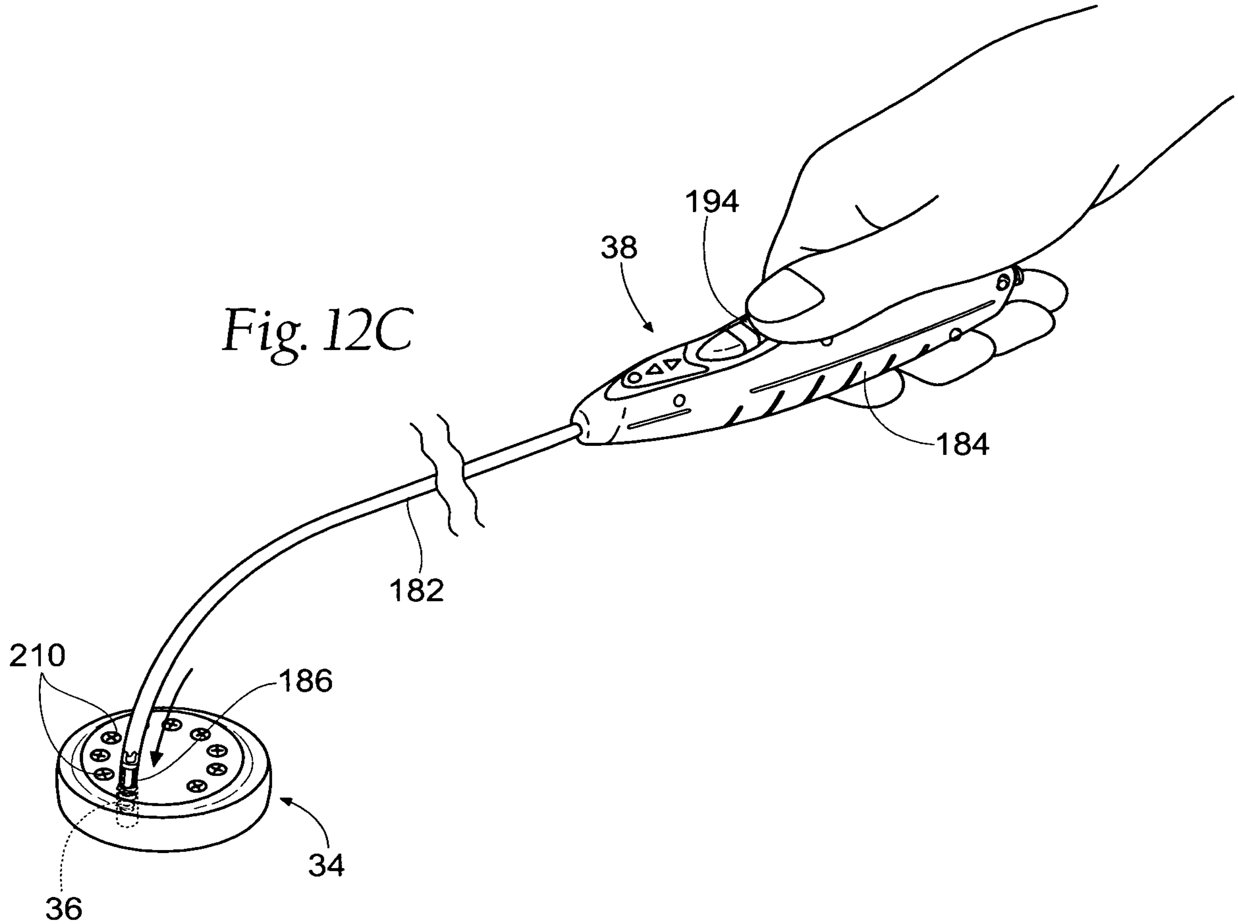


Fig. 12C

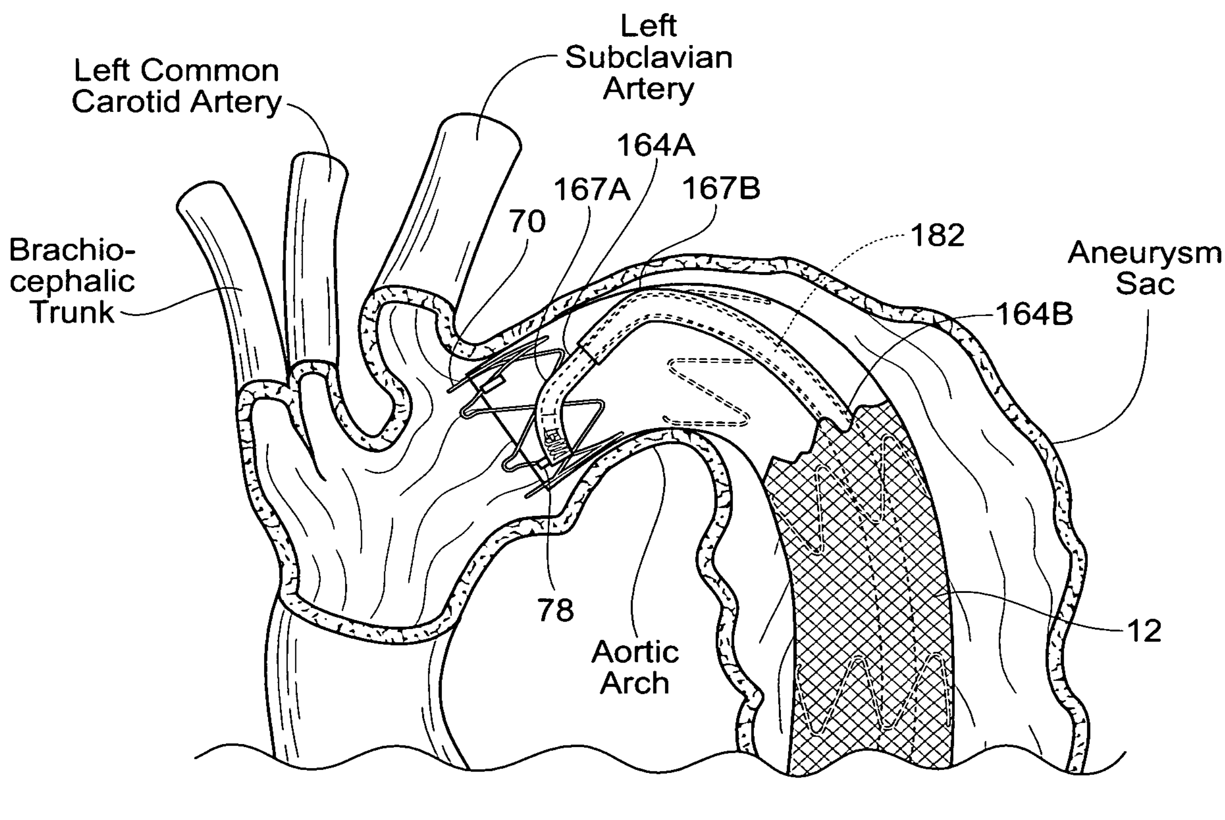


Fig. 13A

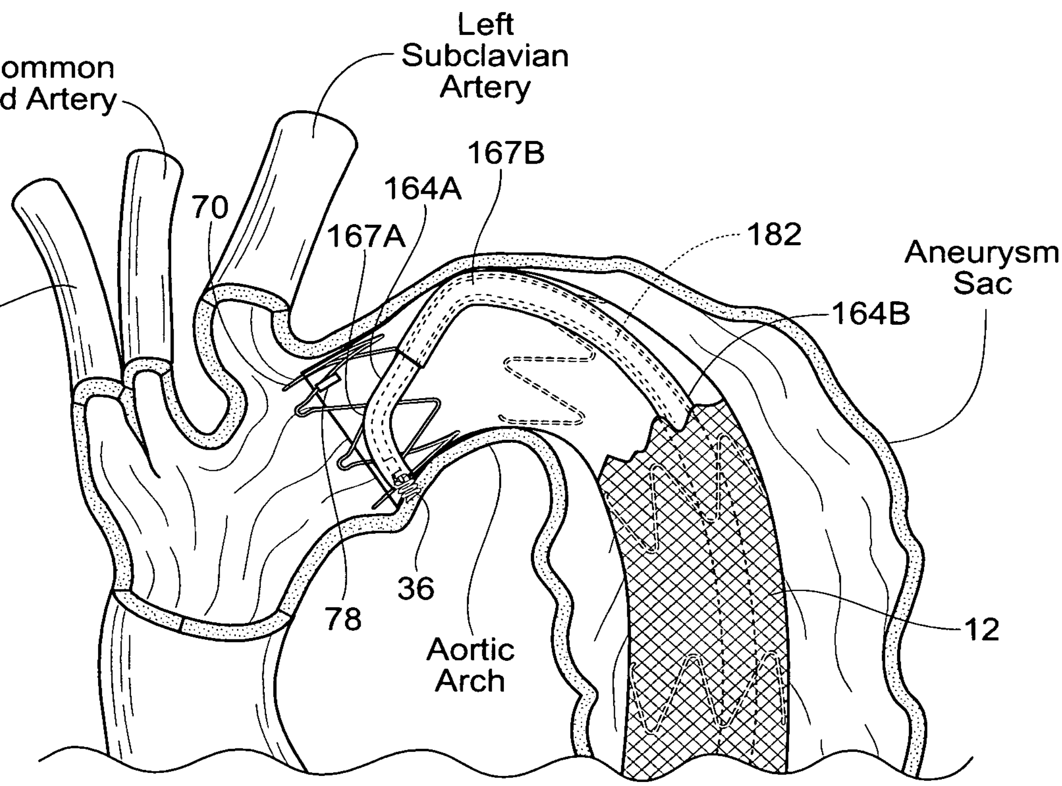

Left Common Carotid Artery
Left Subclavian Artery
Brachio-cephalic Trunk
70
167B
164A
167A
182
Aneurysm Sac
164B
36
78
12
Aortic Arch

Fig. 13B

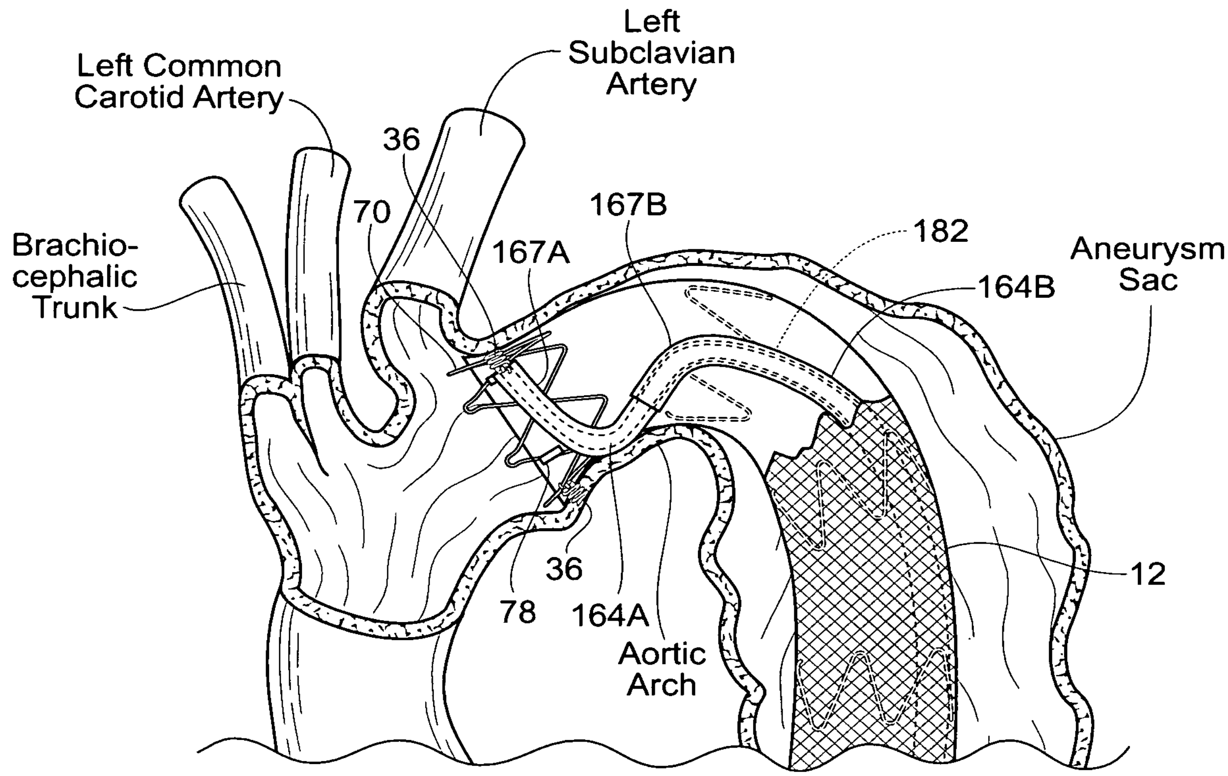


Fig. 13C

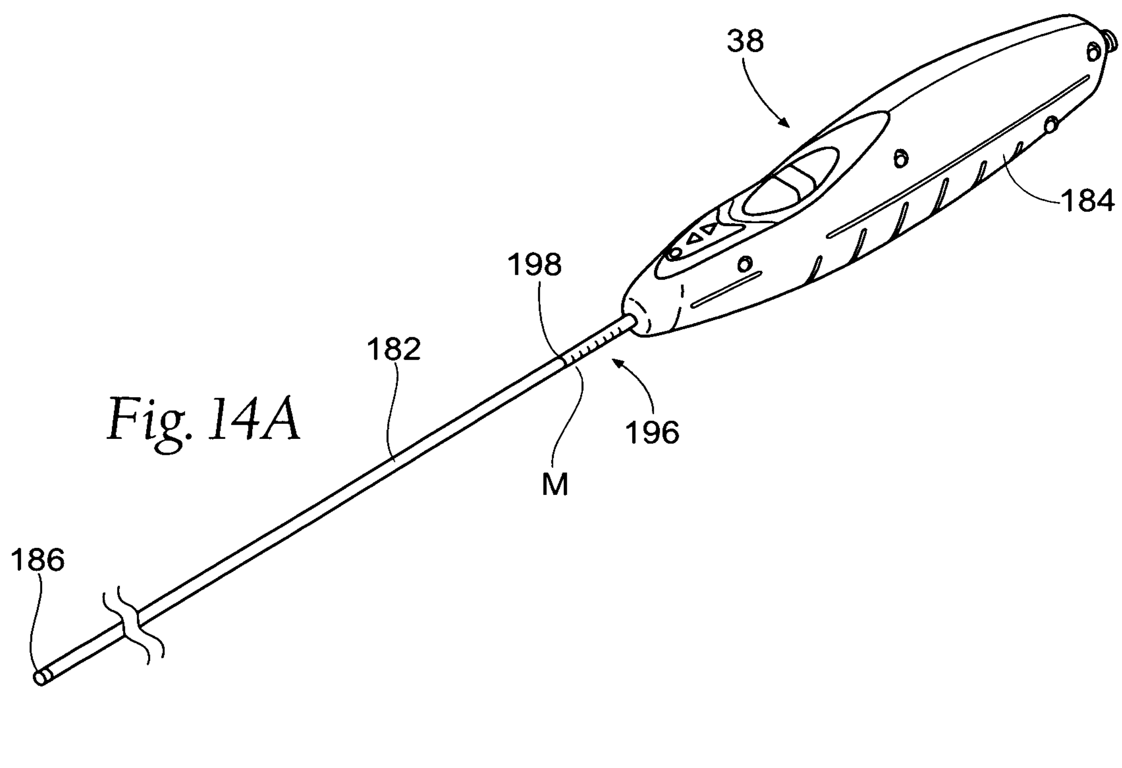


Fig. 14A

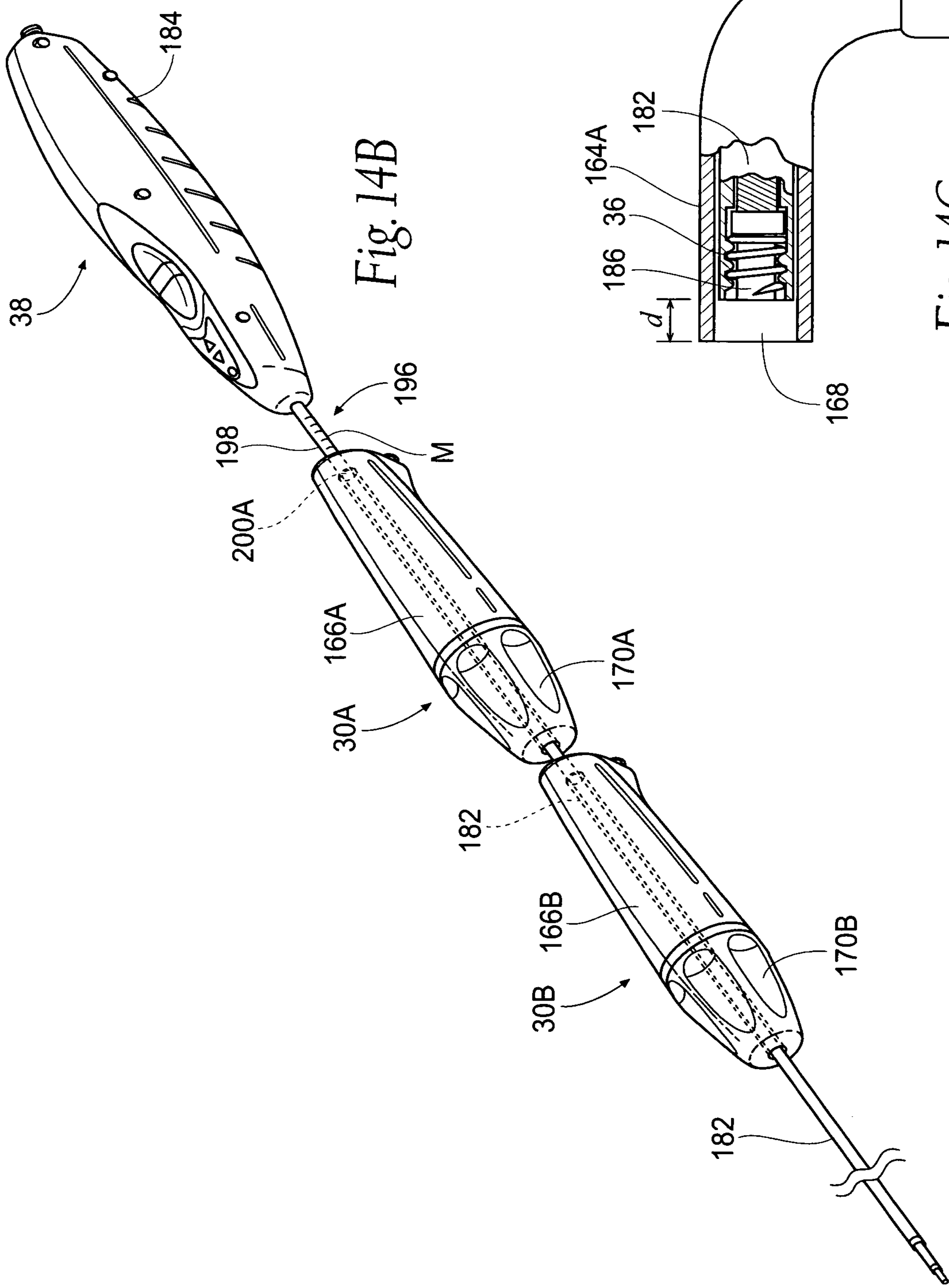


Fig. 14B

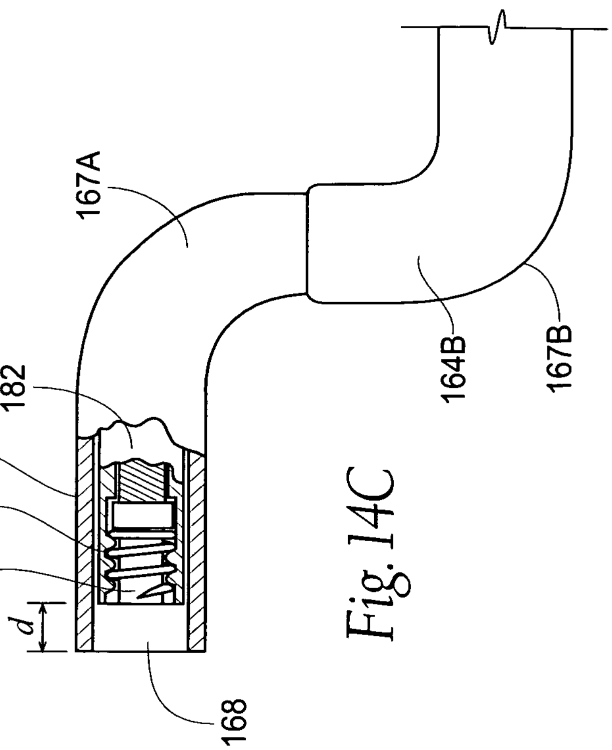


Fig. 14C

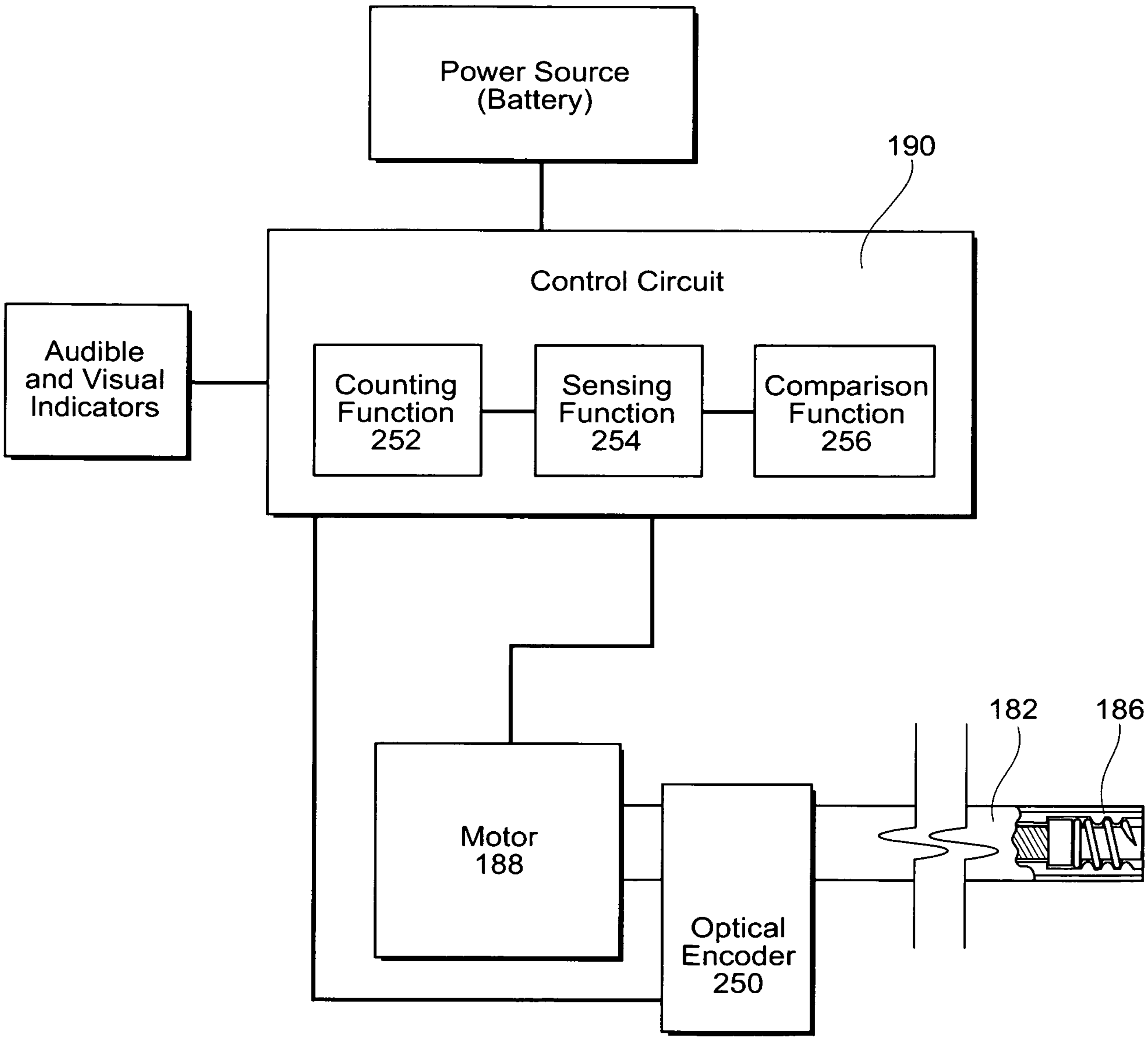
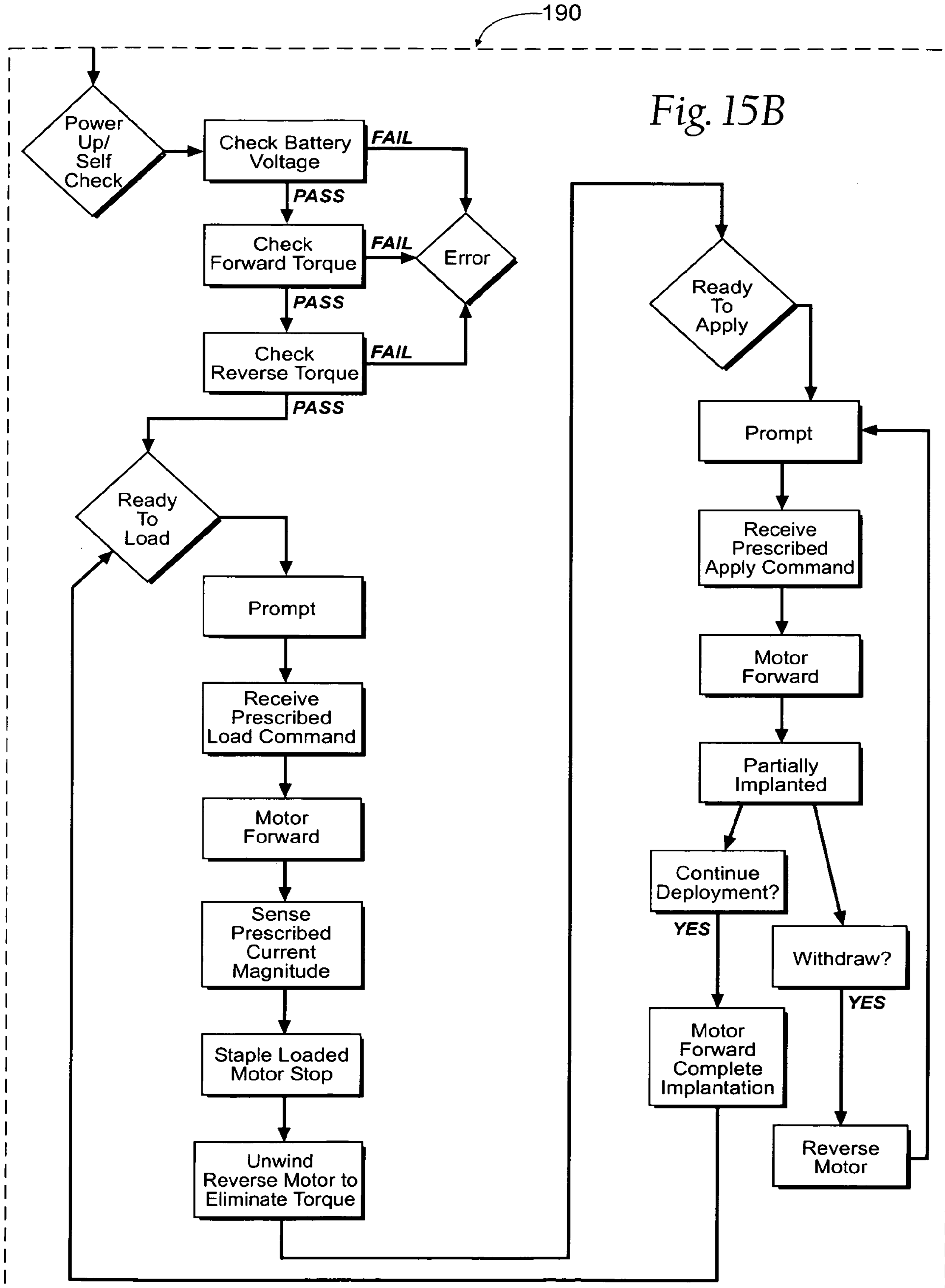

Power Source
(Battery)
190
Control Circuit
Audible
and Visual
Indicators
Counting
Function
252
Sensing
Function
254
Comparison
Function
256
182
186
Motor
188
Optical
Encoder
250

Fig. 15A


190
Fig. 15B
Power Up/ Self Check
Check Battery Voltage
FAIL
PASS
Check Forward Torque
FAIL
Error
PASS
Check Reverse Torque
FAIL
PASS
Ready To Load
Prompt
Receive Prescribed Load Command
Motor Forward
Sense Prescribed Current Magnitude
Staple Loaded Motor Stop
Unwind Reverse Motor to Eliminate Torque
Ready To Apply
Prompt
Receive Prescribed Apply Command
Motor Forward
Partially Implanted
Continue Deployment?
YES
Motor Forward Complete Implantation
Withdraw?
YES
Reverse Motor

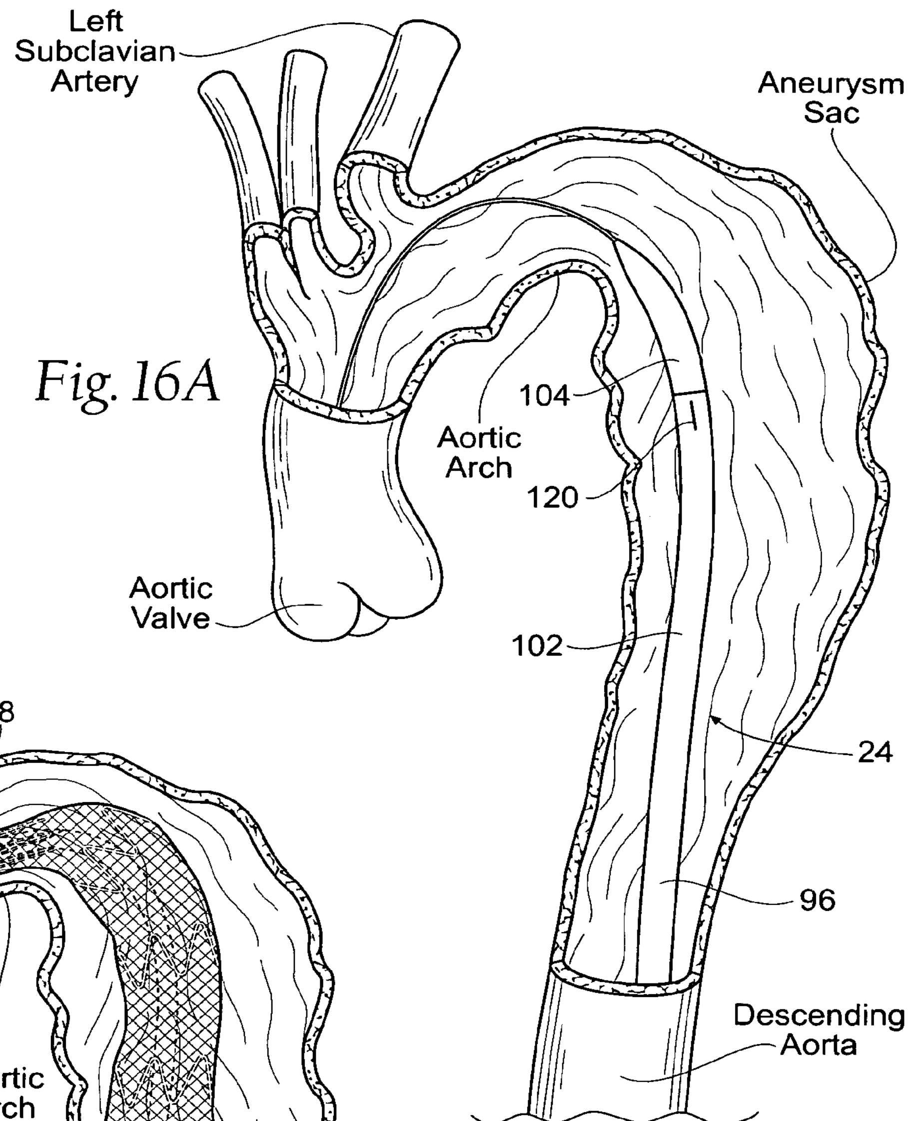


Fig. 16A

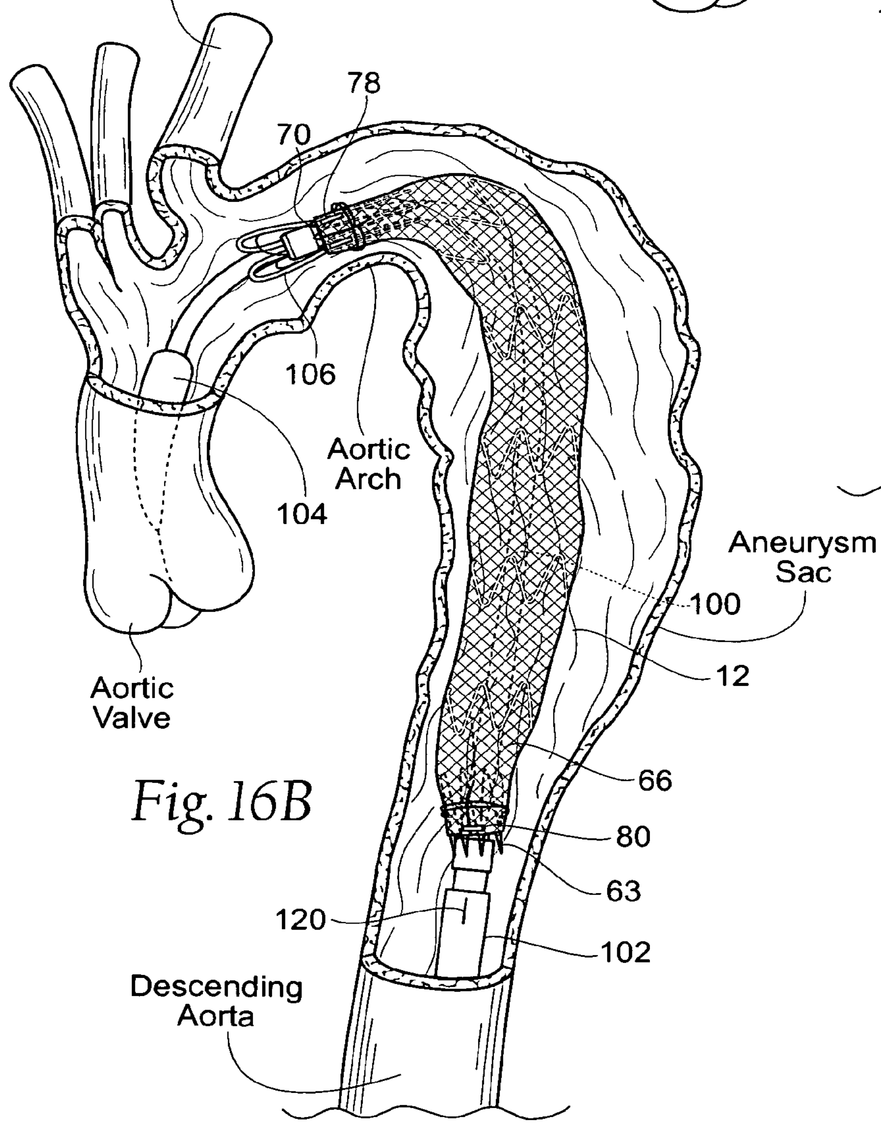


Fig. 16B

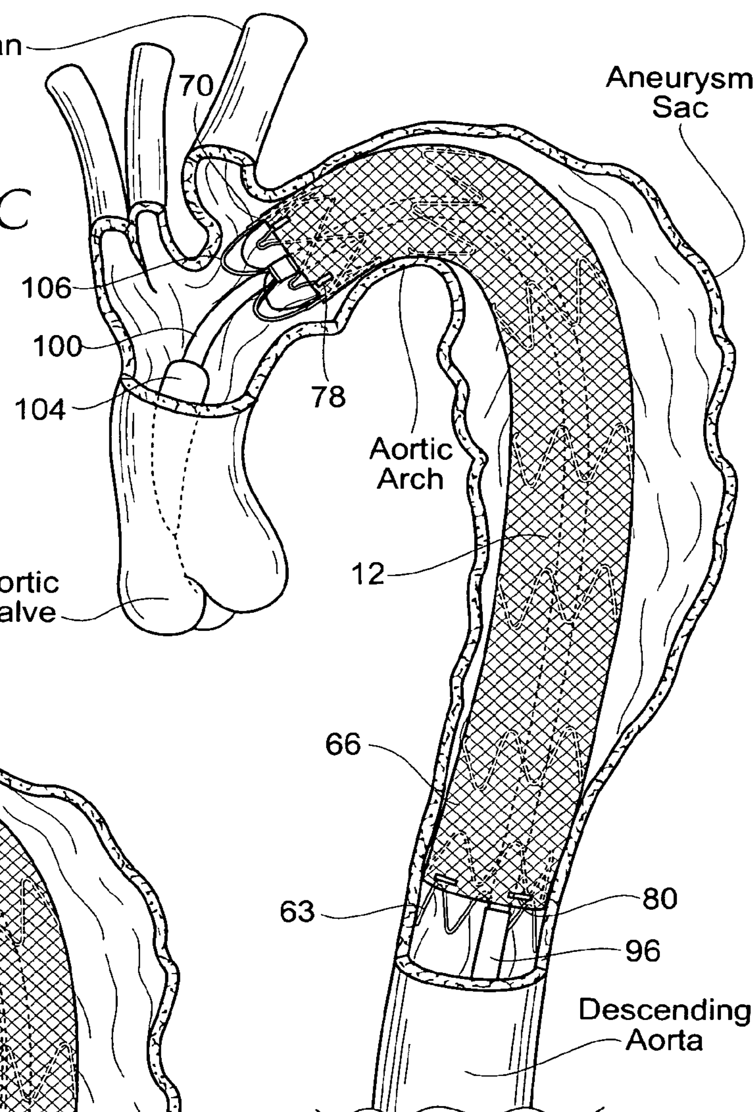


Fig. 16C

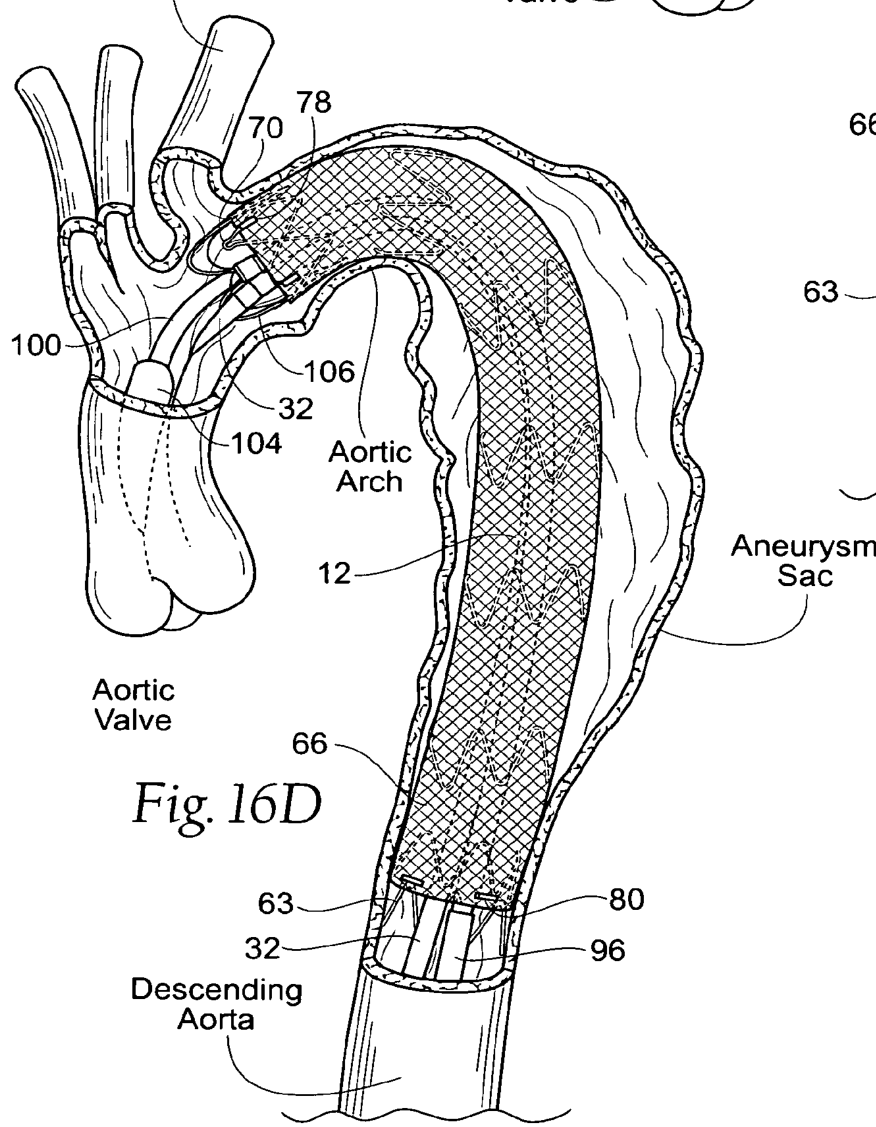


Fig. 16D

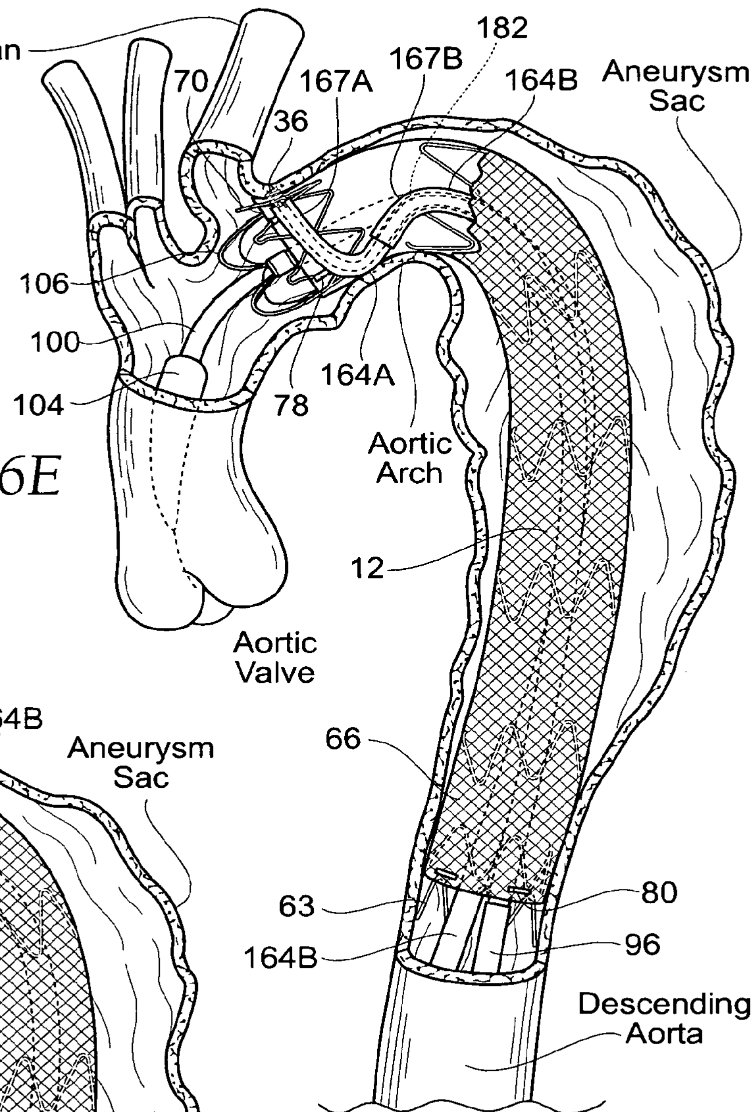


Fig. 16E

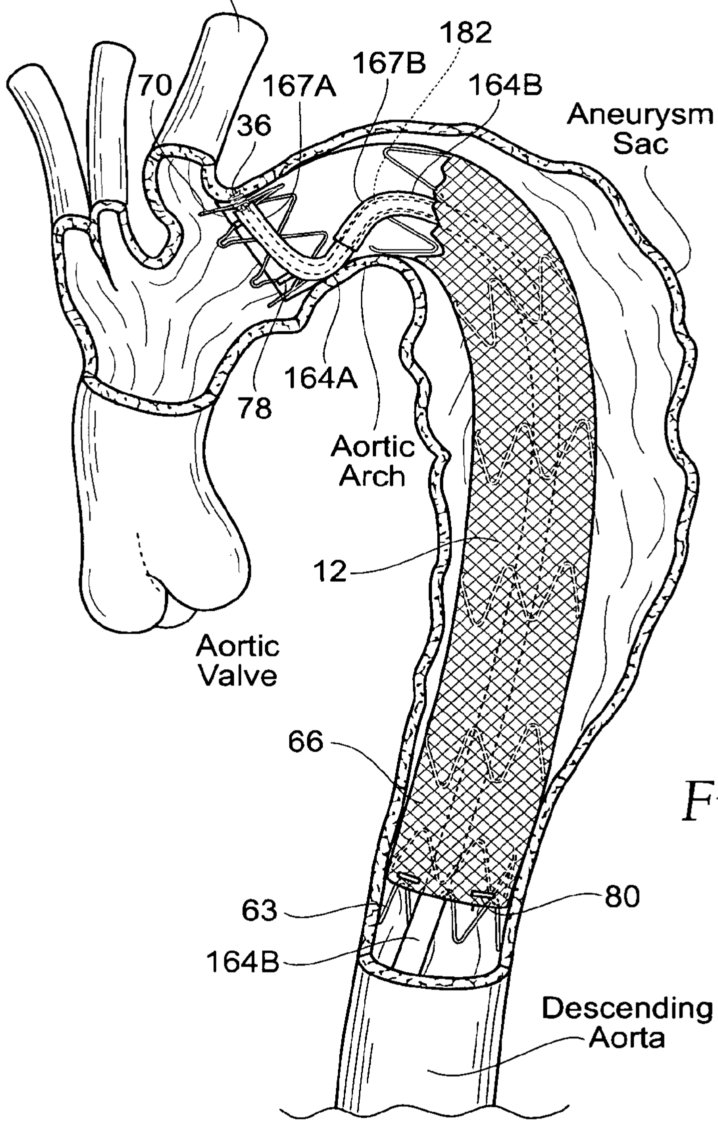


Fig. 16F

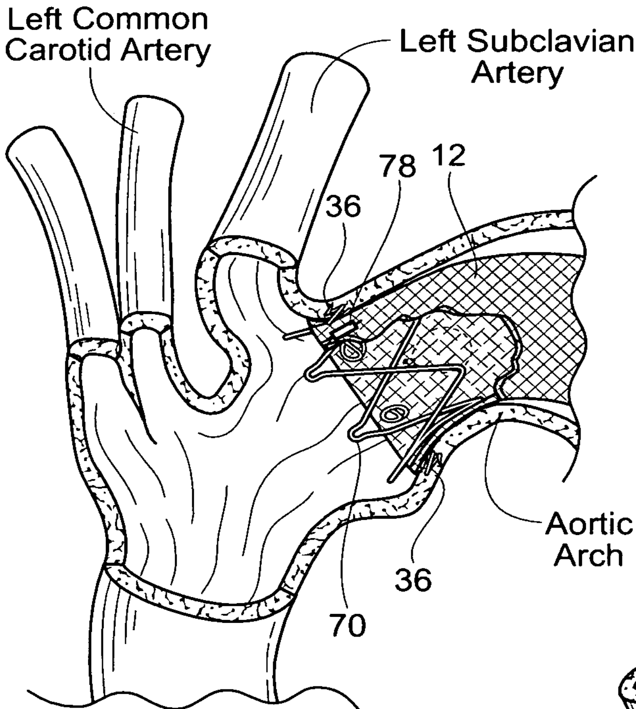


Fig. 16G

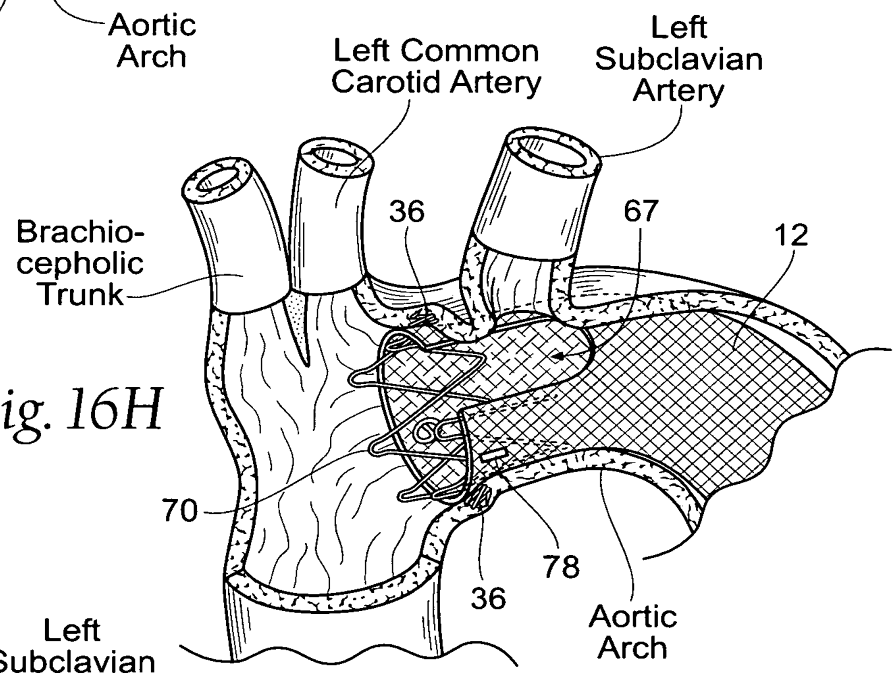


Fig. 16H

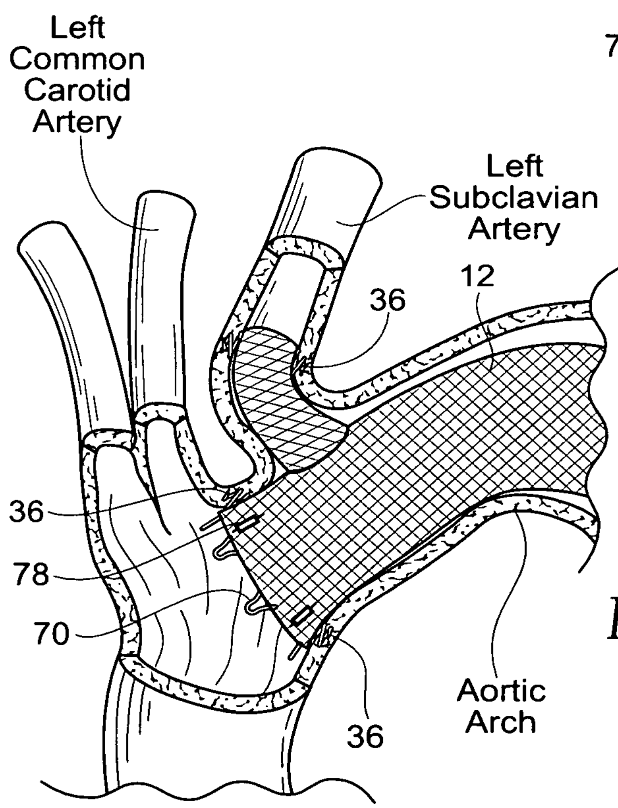


Fig. 16I

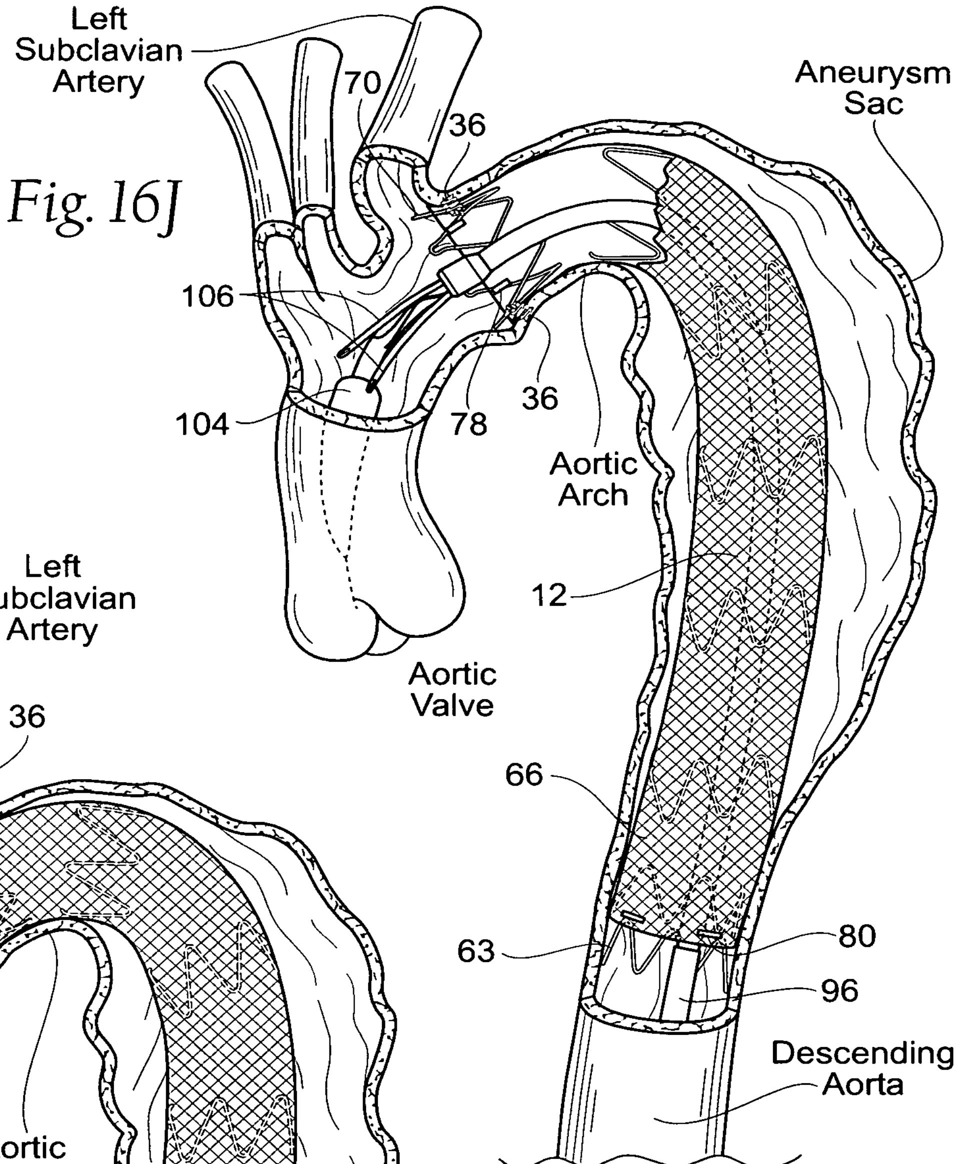


Fig. 16J

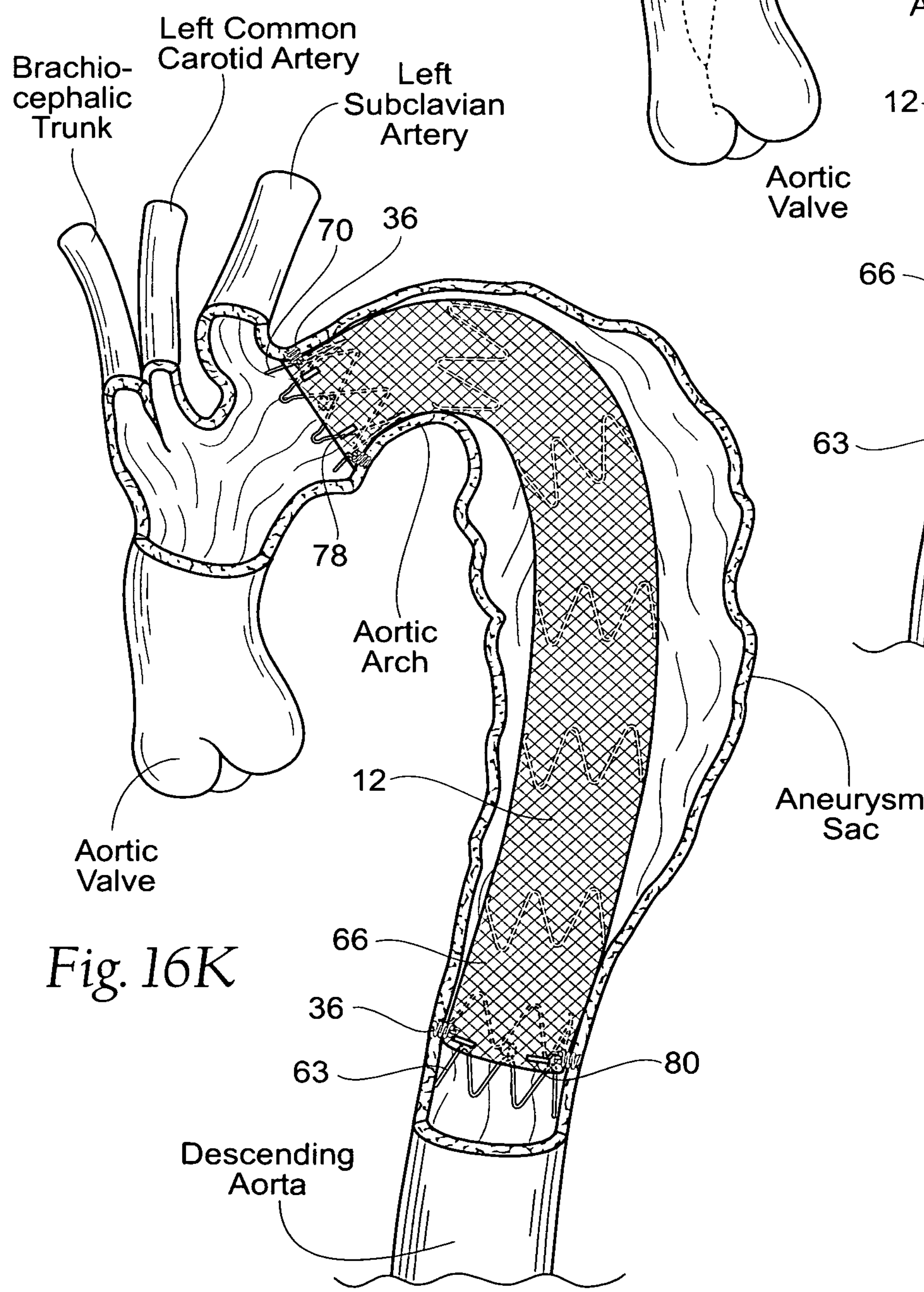


Fig. 16K

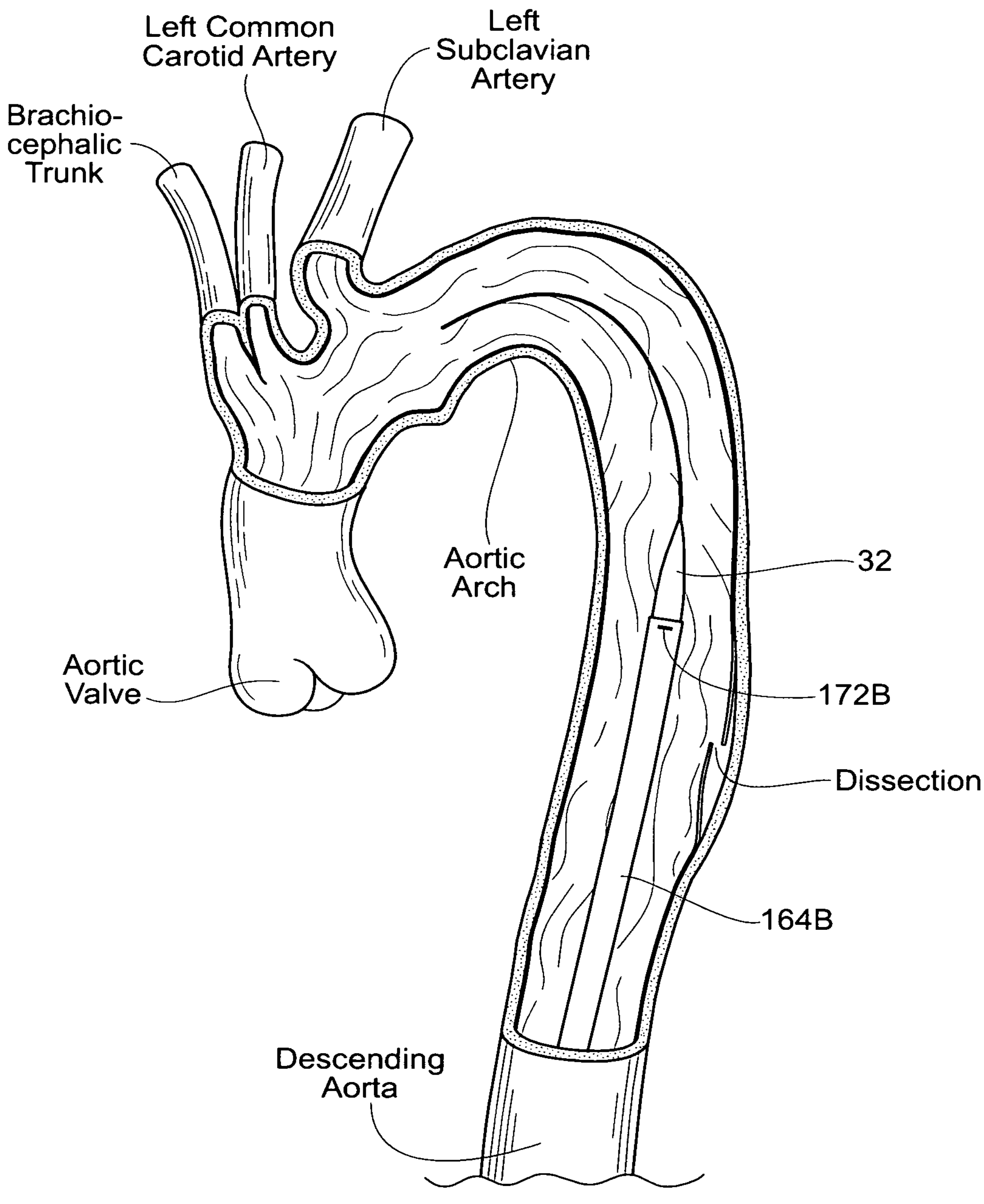

Left Common
Carotid Artery
Left
Subclavian
Artery
Brachio-
cephalic
Trunk
32
Aortic
Arch
Aortic
Valve
172B
Dissection
164B
Descending
Aorta

Fig. 17A

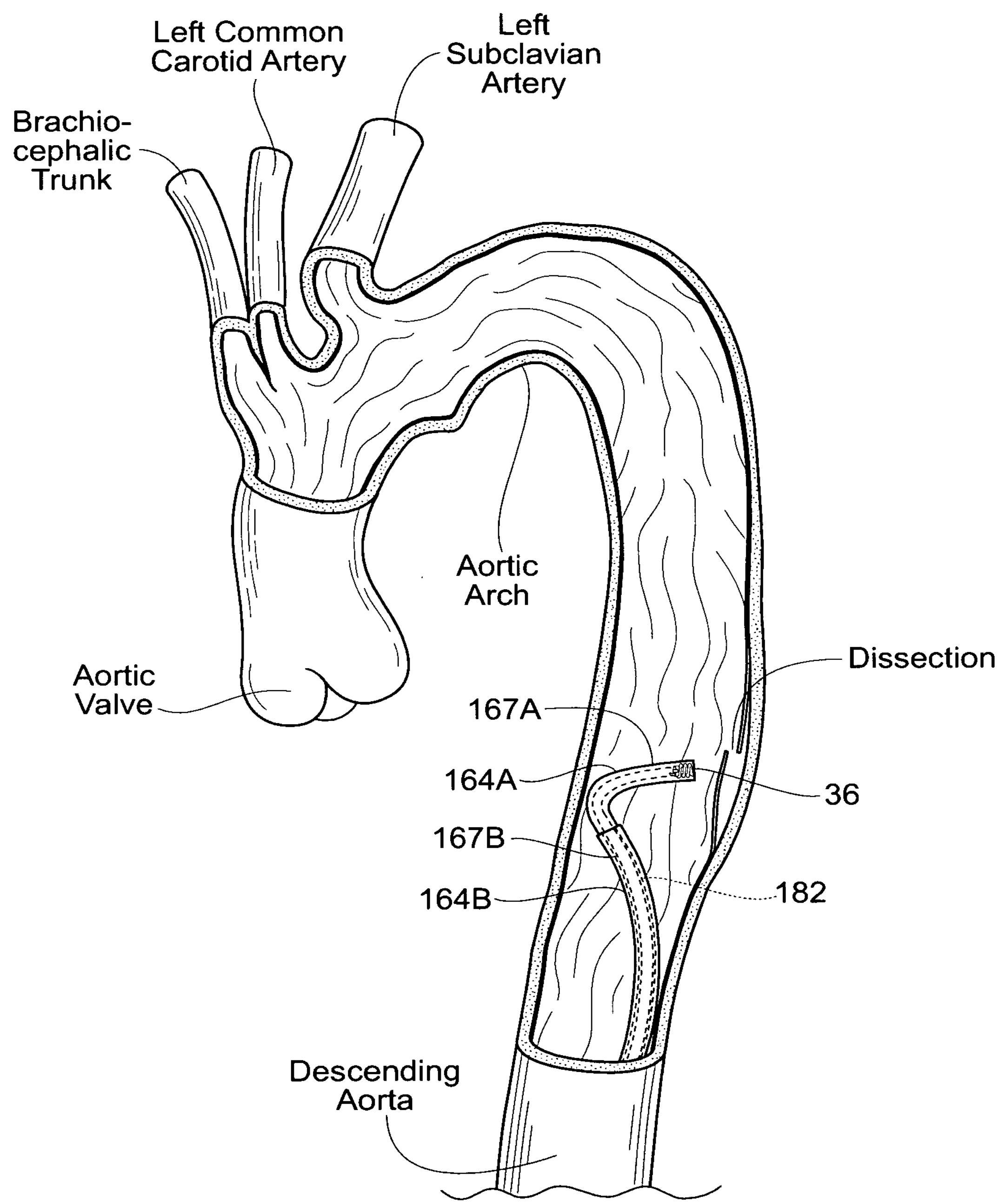

Left Common Carotid Artery
Left Subclavian Artery
Brachio-cephalic Trunk
Aortic Arch
Aortic Valve
Dissection
167A
164A
36
167B
182
164B
Descending Aorta

Fig. 17B

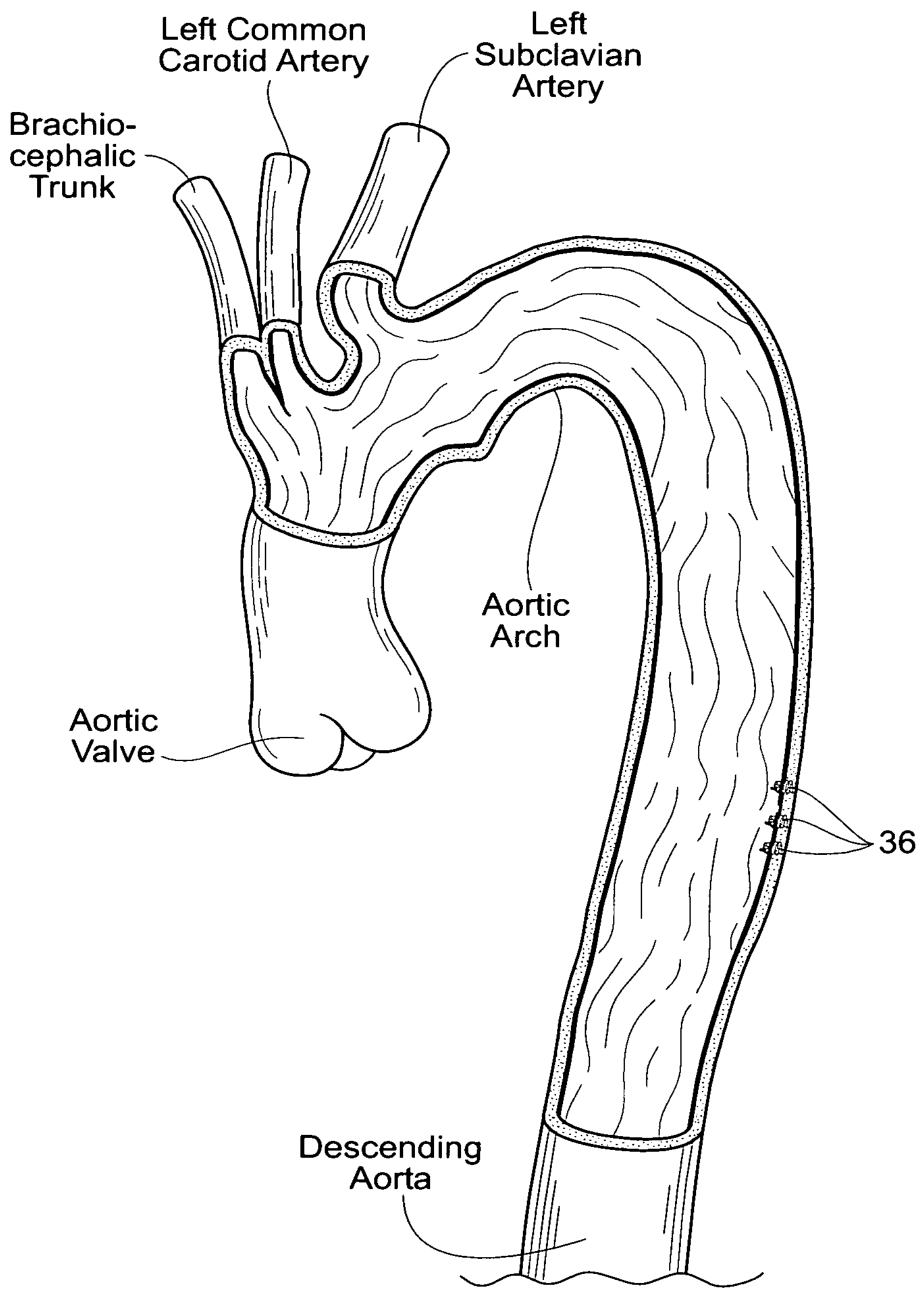

Left Common
Carotid Artery
Left
Subclavian
Artery
Brachio-
cephalic
Trunk
Aortic
Arch
Aortic
Valve
36
Descending
Aorta

Fig. 17C

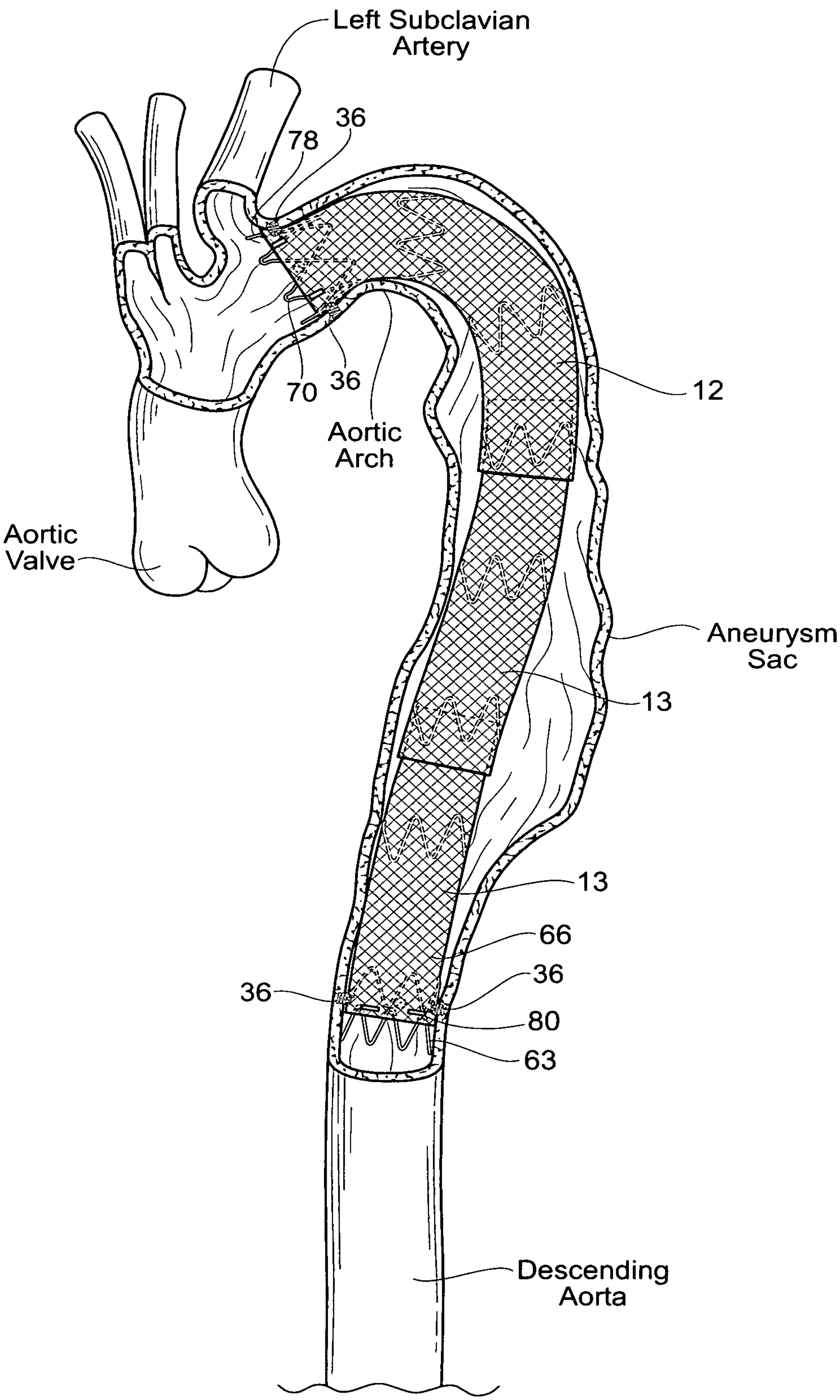

Left Subclavian
Artery
36
78
12
70
36
Aortic
Arch
Aortic
Valve
Aneurysm
Sac
13
13
66
36
36
80
63
Descending
Aorta

Fig. 18A

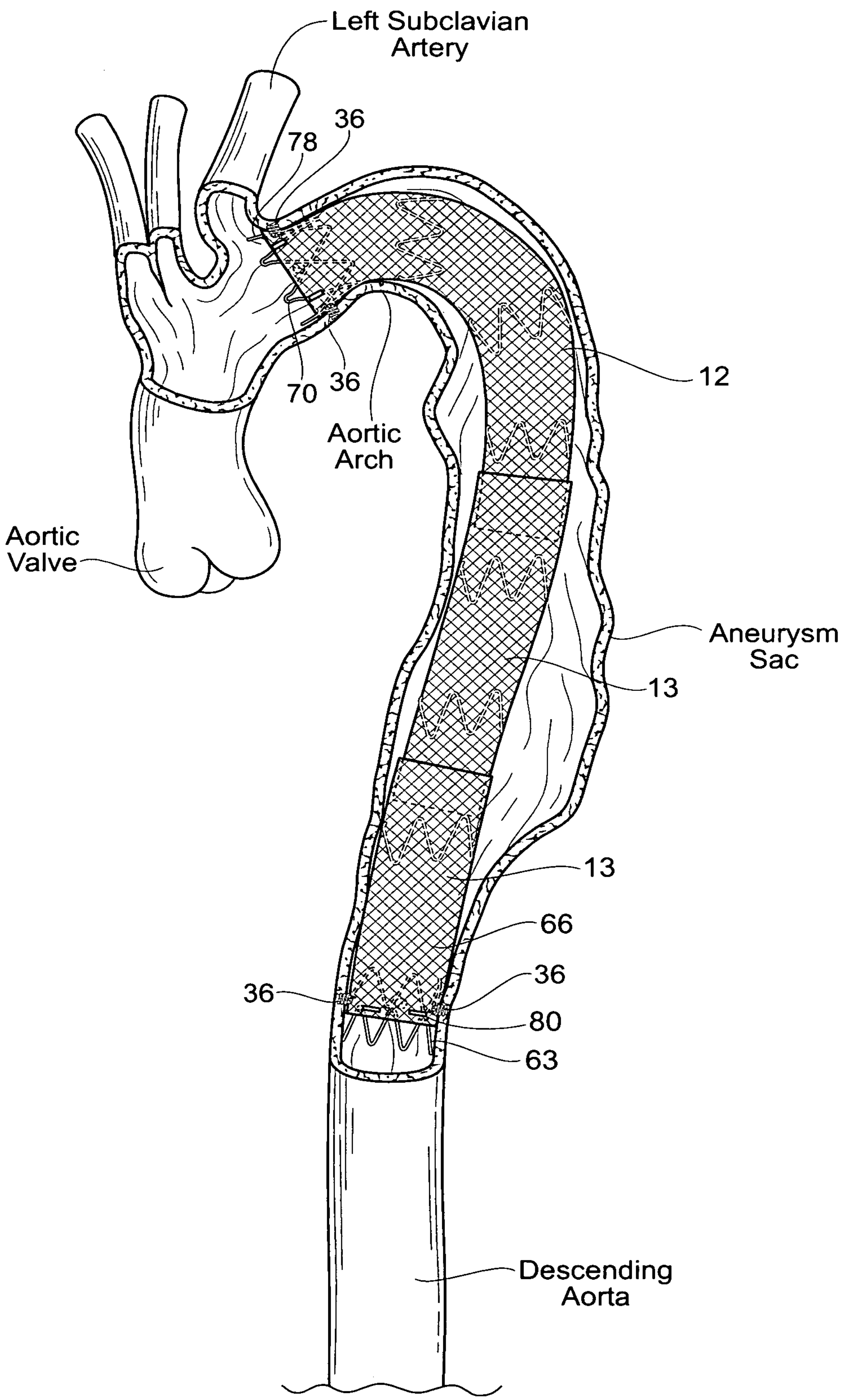

Left Subclavian Artery
78
36
12
70
36
Aortic Arch
Aortic Valve
Aneurysm Sac
13
13
66
36
36
80
63
Descending Aorta

Fig. 18B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 09/05609

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/06 (2009.01)
USPC - 623/1.23; 600/585
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC - A61F 2/06 (2009.01)
USPC - 623/1.23; 600/585

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 600/434, 466

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (DB=PGPB,USPT,USOC,EPAB,JPAB), Google Scholar

Search Terms - graft, stent, staple, vessel wall, catheter, fastener, prosthesis, steerable, guide, staple

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2007/0073389 A1 (BOLDUC ET AL.) 29 March 2007 (29.03.2007) entire document	1, 3-7, 13-20 --- 2, 8-12, 21-22
Y	US 2008/0065189 A1 (BOLDUC) 13 March 2008 (13.03.2008) entire document, especially para [0033]; Fig 11	2, 11-12, 21-22
Y	US 2008/0097489 A1 (GOLDFARB ET AL.) 24 April 2008 (24.04.2008) entire document, especially para [0227], [0232]; Fig 61B	8-10

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
04 December 2009 (04.12.2009)	18 DEC 2009

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774